NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY

SANOFI-AVENTIS U.S. LLC et al.,	:	
Plaintiffs,	:	Civil Action No. 17-9105 (SRC)
v.	:	
MYLAN GMBH et al.,	:	**OPINION**
Defendants.	:	

CHESLER, U.S.D.J.

INTRODUCTION

Plaintiffs Sanofi-Aventis U.S. LLC, Sanofi- Aventis Deutschland GmbH, and Sanofi Winthrop Industrie (collectively, "Sanofi") bring this action for patent infringement against Defendants Mylan GmbH, Biocon Ltd., Biocon Research Ltd., Biocon Sdn. Bhd., and Biocon S.A. (collectively, "Mylan.") Plaintiffs own U.S. Patent No. 9,526,844 ("the '844 patent"), which is listed in the Orange Book as protecting Plaintiffs' Lantus® SoloSTAR® insulin pen product. Mylan GmbH has filed New Drug Application ("NDA") No. 210605 seeking approval to market an insulin pen product. Plaintiffs complain that, by filing this NDA with the United States Food and Drug Administration, Defendants have infringed claims 21, 22, 25, and 30 of the '844 patent. Mylan contends that the asserted patent claims are invalid, pursuant to 35 U.S.C. § 112 ¶ 1 and 35 U.S.C. § 103. A bench trial on patent infringement and patent validity was held for 5 days, beginning on December 2, 2019, and ending on December 6, 2019. Upon hearing

the evidence presented at trial, this Court finds that Sanofi has failed to prove that claims 21, 22, 25, and 30 are infringed by Mylan's NDA product, and Mylan has proven that the asserted claims are invalid for failure to satisfy the written description requirement stated in 35 U.S.C. § 112 ¶ 1.

STIPULATED FACTS

The parties stipulated to the following facts in the Final Pretrial Order ("FPO"):

72. The following documents are prior art to the Device Patents under 35 U.S.C. § 102:

a. U.S. Patent No. 4,865,591 ("Sams")

b. U.S. Patent No. 6,235,004 ("Steenfeldt-Jensen")

c. U.S. Patent No. 5,674,204 ("Chanoch")

d. U.S. Patent No. 6,221,046 ("Burroughs")

e. U.S. Patent No. 7,241,278 ("Møller")

f. U.S. Patent No. 6,248,095 ("Giambattista '095")

g. U.S. Patent No. 6,582,404

h. U.S. Patent App. Pub. No. 2002/0052578

i. EU Patent Specification EP 0 608 343

j. Erdman Arthur G & Sandor, George N., Mechanism Design: Analysis and Synthesis, 110-20 (Prentice Hall 1984)

k. Sclater, Neil & Chironis, Nicholas P., Mechanisms & Mechanical Devices Sourcebook, 191-95 (McGraw Hill, 3d ed. 2001)

l. European Standard EN ISO 11608-1 (Dec. 2000)

THE ISSUES FOR TRIAL

1. Have Plaintiffs proven, by a preponderance of the evidence, that Defendants' NDA product infringes claims 21, 22, 25, or 30 of the '844 patent?

2. Have Defendants proven, by clear and convincing evidence, that claims 21, 22, 25, and 30 of the '844 patent are invalid as obvious, pursuant to 35 U.S.C. § 103?

3. Have Defendants proven, by clear and convincing evidence, that claims 21, 22, 25, and 30 of the '844 patent are invalid for lack of adequate written description, pursuant to 35 U.S.C. § 112 ¶ 1?

4. Have Defendants proven, by clear and convincing evidence, that claims 21, 22, 25, and 30 of the '844 patent are invalid for lack of enablement, pursuant to 35 U.S.C. § 112 ¶ 1?

THE EVIDENCE AT TRIAL

What follows are selected summaries of the testimony of the witnesses appearing in Court at trial:

A. Testimony of Robert Veasey

What follows is a summary of the witness's testimony. Mr. Veasey is a co-inventor, with Robert Perkins and David Plumptre, on the '844 patent. (Tr. 33:25-34:2.) The SoloSTAR® pen injector is a commercial product that came from this project. (Tr. 36:19-21.) The project to develop SoloSTAR® was named "Alpha." (Tr. 38:8-10.) When he began work on the Alpha project, three disposable injector pens were available to consumers, Opti Set, Humalog, and Novo's FlexPen, which was considered better than the others. (Tr. 38:11-22.) The Alpha team studied the FlexPen and measured aspects of it, including the coefficient of

friction. (Tr. 39:2-8.) The coefficient of friction is a measure of the resistance to sliding of two components in contact with each other. (Tr. 40:10-13.) The team derived a coefficient of friction of .15 for the FlexPen, based on the measured value of the most critical friction interface in the device, which was between the dial, the dose dial and the body. (Tr. 40:15-20.) Mr. Veasey told Dr. Slocum that .1 was the lowest realistic value that one could achieve for the coefficient of friction in a high-volume product like SoloSTAR® or FlexPen, if one used tribological grades of polymers, which have additives in them that make them slip particularly well. (Tr. 41:1-10.)

The team studied the FlexPen and found shortcomings, and designed the SoloSTAR® to improve on them. (Tr. 42:4-20.) In the real world, the coefficient of friction affects the amount of force a user must use to depress the pen button. (Tr. 44:4-16.) One goal for the design project was a pen with low injection force, because the elderly diabetes population has lower hand strength. (Tr. 46:15-47:15.) Another goal was a pen that had a maximum insulin dose of 80 units or more. (48:10-16.) SoloSTAR® is about 40 percent lower injection force than FlexPen. (Tr. 50:20-21.) The ’844 patent embodies the team’s design concept 12. (Tr. 56:25-57:1.) A patent application for the SoloSTAR® design was filed in Great Britain in March of 2003, and it has essentially the same specification as the ’844 patent has. (Tr. 57:9-23.)

The OptiClik was a reusable pen injector from Sanofi with a very different mechanism from SoloSTAR®. (Tr. 58:7-13.) To date, about 3 billion SoloSTAR® pens have been sold. (Tr. 61:4-5.) The SoloSTAR® has been awarded a number of industry awards. (Tr. 61:6-23.)

On cross-examination, Mr. Veasey said that he held an actual FlexPen at the end of 2001. (Tr. 64:1-11.)

B. Testimony of Charles Reinholtz

What follows is a summary of the witness's testimony. Dr. Reinholtz was qualified as an expert in mechanical engineering mechanisms as it relates to the issues of infringement in this case. (Tr. 89:15-20.) Dr. Reinholtz identified exhibit PTX-894 as the assembled Semglee[1] pen. (Tr. 92:12-14.) Becton Dickinson is the company that designed the Semglee pen. (Tr. 93:16-20.) As to '844 claim 21, the parties have agreed that only three elements are disputed as to infringement; the first is 21e. (Tr. 97:4-25.)

Limitation 21e states: "A sleeve that is disposed between the dose indicator and the driving member and releasably connected to the dose indicator." (Tr. 97:25-98:2.) The parties' dispute over 21e concerns the "releasably connected" limitation. (Tr. 98:3-6.) Defendants have taken the position that this means connected when the device is in a resting state, but Dr. Reinholtz disagreed with this. (Tr. 98:7-13.) He disagreed because the claim limitation does not require it to be connected in any particular state. (Tr. 98:15-16.)

The language of limitation 21e does not require that the sleeve is connected to the dose indicator during dose setting or injection. (Tr. 98:17-23.) The sleeve in the patent claims is called the setback in the Semglee, and the dose indicator is called the dose set knob in the Semglee. (Tr. 99:4-16.) In the Semglee, the setback is releasably connected, in rotation, to the dose set knob. (Tr. 99:17-23.) The NDA for the Semglee says that, when the user dials up a dose, there is no pressure on the button to lock the DSK and setback together so that the DSK can rotate freely whilst the setback remains rotationally static. (Tr. 100:17-24.) Then, to

[1] "Semglee" is one of the names used to refer to Mylan's accused pen, which is also called "Vystra." "Vystra" is the name that this Opinion will generally use for Mylan's accused device.

deliver a dose, the user pushes a button and this locks those two components together so they're connected and they rotate together. (Tr. 100:25-101:2.) When the user releases the button, the rotatable connection is released. (Tr. 101:7-10.) The Semglee pen practices limitation 21e. (Tr. 102:8-10.)

As to limitation 21f, the parties dispute whether the piston rod must be solid or may be hollow. (Tr. 102:22-25.) The Semglee has a hollow piston rod. (Tr. 103:1-2.) A hollow rod is still a rod. (Tr. 103:5-6.) Nothing in the '844 patent requires the piston rod to be solid, nor precludes it from being hollow. (Tr. 103:7-12.) Limitation 21f says the rod can have an internal thread, which requires a portion that is hollow. (Tr. 103:13-18.) Limitation 21f refers to a third thread, which is on the driving member in claim 21, or the lead screw in the Semglee. (Tr. 104:2-9.) The plunger rod in the Semglee has either an internal or an external fourth thread that is engaged with the third thread of the lead screw. (Tr. 104:10-18.) The plunger rod in the Semglee pen advances the piston. (Tr. 105:8-10.) The Semglee pen practices limitation 21f. (Tr. 106:8-11.)

As to limitation 21g, the piston rod holder of claim 21 is the component in the Semglee called the tower core. (Tr. 106:22-25.) Defendants dispute that the tower core is the claimed piston rod holder, and also whether it is configured to prevent the piston rod from rotating during dose setting. (Tr. 107:1-7.) Defendants dispute whether the tower core holds the piston rod in the Semglee, and also that the tower core is configured to prevent rotation during dose dispensing. (Tr. 107:10-21.) "Hold" means to constrain, so as to remove degrees of freedom from one part relative to another. (Tr. 108:1-3.) There is a slot in the tower core that engages with a tab in the piston rod, and the engagement is like a keyed connection that only allows the

piston rod to slide axially relative to the tower core; it does not allow it to rotate relative to the tower core or move side to side relative to the tower core. (Tr. 108:7-16.) The tower core holds the plunger rod against rotation, and prevents it from moving side to side, so it is therefore a piston rod holder. (Tr. 109:7-14.) In the Semglee, the tower core is configured to prevent the plunger rod from rotating during dose setting because it's configured to prevent it from rotating at all times when the pen is assembled. (Tr. 109:18-21.) The Semglee NDA states that the tower core is keyed to the plunger rod and prevents it from rotating when the lead screw rotates during dose delivery, which confirms this. (Tr. 110:1-11.) If the keyed connection were not present, the plunger rod could rotate during dose setting. (Tr. 110:22-25.) Dr. Reinholtz did an experiment that confirmed this. (Tr. 111:16-114:15.) The tower core is a piston rod holder that is configured to prevent the piston rod from rotating during dose setting. (Tr. 115:6-9.)

Limitation 21g also requires that the piston rod holder is rotatably fixed relative to the housing. (Tr. 115:13-16.) In the Semglee, it is labeled the upper body housing, and the tower core is rotatably fixed relative to it. (Tr. 115:17-24.) The tower core snaps into the brake tower, and the brake tower stays fixed with respect to the housing. (Tr. 115:25-116:2.) Once assembled, these three pieces are locked together. (Tr. 116:3-4.) The Semglee NDA confirms that the housing retains the brake tower, which retains the tower core; the three components cannot move relative to one another. (Tr. 116:8-22.)

Limitation 21g also requires that the piston rod holder be configured to permit the piston rod to traverse axially toward the distal end during dose dispensing, and it isn't disputed that the Semglee practices this. (Tr. 117:6-12.) The Semglee NDA confirms that the plunger rod traverses axially toward the distal end during dose dispensing. (Tr. 117:17-118:1.) The

Semglee tower core is a piston rod holder configured to permit the piston rod to traverse axially toward the distal end during dose dispensing. (Tr. 118:4-7.) The Semglee practices the limitation in 21g and claim 21 is infringed by the accused device. (Tr. 118:10-21.)

Dependent claim 22 requires the device of claim 21 where the piston rod has a circular cross-section, and the Semglee plunger rod does, as the picture shows. (Tr. 119:14-20.) It is a cylinder along its length. (Tr. 119:24.) A wide feature at its distal end is a pressure foot, and it is an integral, molded part of the plunger rod. (Tr. 120:3-13.) Claim 22 is infringed by the Semglee. (Tr. 120:18.)

Claim 23 recites the device of claim 21 further comprising a clutch, which is the setback in the Semglee. (Tr. 120:24-121:8.) When the user presses the button, the dose set knob and the setback are locked in rotation; the setback is both the sleeve of claim 21 and the clutch of claim 23. (Tr. 121:13-21.)

Claim 24 recites the device of claim 23 where the clutch provides audible and tactile feedback indicative of unit doses of medicament; the setback has teeth, and those teeth interact with a pair of arms that have teeth on them, part of the double clicker. (Tr. 122:6-123:6.) The relative rotation of these components causes a clicking sound and tactile feedback. (Tr. 123:7-9.) Each click corresponds to one unit dose of medication, so each is indicative of unit doses of medicament. (Tr. 123:13-17.)

Claim 25 recites the device of claim 24 where the clutch provides audible clicks during dose canceling, where each click is equal to a unit dose of medicament, and the setback does that during dose cancelling. (Tr. 124:14-21.) Claim 25 is infringed by the Semglee. (Tr. 125:8.)

Claim 30 recites the device of claim 21 further comprising a nut that tracks each set dose

of medicament delivered; in the Semglee, this nut is called the dose stop. (Tr. 125:13-19.) The parties dispute whether the dose stop is a nut in part because it has external threads. (Tr. 125:21-24.) Defendants contend that the nut must have internal threads, but some nuts have external threads -- flare nuts, as well as lug nuts in automobiles have only external threads. (Tr. 125:25-126:7.) Defendants also question whether the dose stop is a nut because it does not wrap around in a full circle. (Tr. 126:15-18.) A nut that wraps around in a full circle is a full nut, while a nut that wraps around halfway would be a half nut or partial nut. (Tr. 126:19-24.) The '844 patent specification states that the nut 40 in figure 5 is a half-nut. (Tr. 127:3-10.) The Semglee dose stop is a nut, even though it is not a full nut. (Tr. 127:16-18.)

Claim 30 also requires that the nut tracks each set dose of medicament delivered, and the dose stop does this. (Tr. 127:19-23.) The nut threads along the axis of the pen as the user dials a dose and ultimately prevents the user from dialing a dose that exceeds what is available. (Tr. 128:4-11.) The nut moves along the pen to track each set dose of medicament delivered. (Tr. 128:16-20.) Exhibit PTX-394 confirms that the dose stop rides along with the dose set knob to track doses. (Tr. 129:1-8.) Claim 30 is infringed by Semglee. (Tr. 129:11-15.)

On cross-examination, Dr. Reinholtz stated that he had not published any paper that talked about injector pens, nor had he ever done research (prior to this case) on them, nor designed any. (Tr. 130:11-131:1.) When the Semglee is at rest, the sleeve and dose set knob, or dose indicator, are not connected. (Tr. 132:5-11.) In the '844 patent figures showing the embodiment, the sleeve and dose indicator are coupled when the device is at rest; when the user depresses the button, those two components become uncoupled. (Tr. 133:14-24.) Thus, in the '844 embodiment, at rest, the sleeve is connected to the dose indicator; in the Semglee, the

setback and dose set knob become coupled only upon pressing the button. (Tr. 133:25-134:12.)

As to the hollow rod, the Semglee has a hollow piston rod, which could be called a tube, a cylinder, or a sleeve. (Tr. 137:12-21.) The '844 patent does not disclose an embodiment with a hollow tube as a rod. (Tr. 137:22-25.)

The term "holder" does not appear in the '844 patent except in the claim. (Tr. 138:21-139:2.) When Dr. Reinholtz did his experiment on the tower core, he used a knife to cut off the part of the tower core that is the slotted portion that resides inside the piston rod tube. (Tr. 139:9-24.) After he did the cut, he reassembled the pen without the dose stop nut. (Tr. 141:5-7.) The Semglee's setback serves the functions of both the sleeve and the clutch in the patent. (Tr. 150:1-20.)

Most of the nuts we're familiar with day to day are internally threaded. (Tr. 152:10-13.) The nut shown in the '844 patent is internally threaded. (Tr. 153:9-11.) A pipe nipple, depending on how it's used, could be considered a nut, but Dr. Reinholtz would not generally describe it as a nut. (Tr. 154:7-21.)

On redirect examination, Dr. Reinholtz said that limitation 21f allows for a hollow piston rod. (Tr. 155:17-22.)

C. Testimony of Robin Goland

What follows is a summary of the witness's testimony. Dr. Goland was admitted as an expert in endocrinology and treatment of patients with diabetes. (Tr. 159:25-160:4.) Taking injections is hard for everybody, and the need to use your hands and complicated self-care techniques makes it harder, so it is important to have an easy-to-use pen to administer insulin. (Tr. 162:10-18.) Prior to the launch of the SoloSTAR® pen, Lantus was administered to

patients with the OptiClik pen, and Levemir with the FlexPen. (Tr. 163:5-17.) These pens were not easy to use. (Tr. 163:18-19.) The OptiClik was not easy to use because it was big, not disposable, people struggled to replace the cartridge and see the numbers, and they had trouble pressing the button. (Tr. 163:23-164:5.) The FlexPen was not easy to use because the dose stop didn't work properly, and it was a lot harder to push. (Tr. 164:8-16.) Because of the problems with OptiClik and FlexPen, there was a need for an easy-to-use pen with a low injection force in 2007, and SoloSTAR® met that need. (Tr. 164:23-165:3.) The improvement from the OptiClik to the SoloSTAR® was dramatic. (Tr. 165:4-6.) Prior to the launch of the SoloSTAR®, patients would look at the vial and syringe and say it was too scary. (Tr. 165:14-18.) The SoloSTAR® is discreet, can be carried in the pocket, is disposable, very easy to push, the numbers are easy to read, and you can hear the dose as you dial it up. (Tr. 166:5-14.) The low injection force of the SoloSTAR® helped patients with limited dexterity, and Dr. Goland switched patients to SoloSTAR® because of its low injection force and ease of use. (Tr. 167:7-12.) The SoloSTAR® can administer up to 80 units in an injection, whereas previous pens had a maximum of 60 units. (Tr. 167:13-20.) Dr. Goland never encountered a patient who had difficulty using the SoloSTAR®. (Tr. 168:5-8.) None of her patients switched to SoloSTAR® based on her handing out marketing samples. (Tr. 170:5-8.)

On cross-examination, Dr. Goland said that the OptiClik had many issues, was actually defective, a very bad pen, did not deliver accurately, was big, and the numbers were hard to read. (Tr. 171:7-21.) The SoloSTAR® satisfied a long-felt need. (Tr. 172:7-10.) Dr. Goland did not review the '844 patent and does not know what it says. (Tr. 172:17-173:10.) When insulin glargine was launched, it met a long-felt and unmet need. (Tr. 173:11-18.) Sanofi also sells

Apidra, a short-acting insulin, in the SoloSTAR® pen. (Tr. 174:5-10.) The only available Lantus pen product is the SoloSTAR®. (Tr. 176:3-6.) Patients all notice the injection force of the SoloSTAR®, and they're very happy that it's so much easier than expected. (Tr. 177:2-6.)

On redirect examination, Dr. Goland agreed that, were Apidra offered in the OptiClik pen, the SoloSTAR® pen with Apidra would be an improvement over it. (Tr. 178:14-16.)

D. Testimony of Henry Grabowski

What follows is a summary of the witness's testimony. Dr. Grabowski was admitted as an expert in the field of economics, including pharmaceutical and health economics. (Tr. 189:8-13.) Dr. Grabowski said that his assignment in this case was to determine using economic data whether SoloSTAR® was a commercial success and also whether there was a nexus to the patent at issue, and he concluded that SoloSTAR® is a commercial success and there is a nexus to the patent at issue. (Tr. 189:18-25.)

When Lantus SoloSTAR® was introduced in 2007, it immediately became the market leader and, by its second full year on the market, it had more than 60% market share among long-acting pens. (Tr. 191:3-10.) The FlexPen flatlined at about 30% share after SoloSTAR® was introduced. (Tr. 191:11-15.) After SoloSTAR® was introduced, the number of prescriptions written rapidly grew much faster than the other long-acting pens in the market, and it is the most-prescribed long-acting insulin pen product since 2008. (Tr. 191:23-192:7.) By 2013, it became the market leader among all insulin injectable products. (Tr. 192:18-19.) Over all the years, it has had gross sales of more than $40 billion. (Tr. 194:21.) Lantus SoloSTAR® has been successful not only in terms of insulin injectable products, but it has been one of the most successful introductions in the last 15 years. (Tr. 193:22-194:2.)

As to the nexus between the commercial success of SoloSTAR® and the three claims of the ’844 patent, Dr. Grabowski compared Lantus SoloSTAR® to Lantus OptiClik, and the SoloSTAR® practices the ’844 patent while the OptiClik does not. (Tr. 195:1-21.) While the two products have the same insulin, SoloSTAR® dramatically outperformed OptiClik, which was eventually discontinued in 2012. (Tr. 196:8-15.) Dr. Grabwski also compared Apidra in OptiClik with Apidra in SoloSTAR®, and SoloSTAR® was prescribed several multiples more than the OptiClik version. (Tr. 196:23-197:8.) This confirms the view that the features enabled by the ’844 patent were a driving factor in the performance of SoloSTAR®. (Tr. 197:12-15.) These comparisons show that the performance of SoloSTAR® was not due to the insulin it delivered. (Tr. 197:16-24.) Dr. Grabowski did not, however, attempt to apportion the commercial success among the various factors that have contributed to it. (Tr. 199:8-11.) A study by Clarke and Spollett showed that the injection force of SoloSTAR® was 30% lower than that of FlexPen. (Tr. 201:13-18.) Two award press releases mention low injection force. (202:23-204:3.)

Dr. Grabowski disagrees with Dr. McDuff’s positions about blocking patents because the blocking patents cover insulin glargine, not pens. (Tr. 205:2-5.) And the blocking patents expired in 2014-2015, so they have not been in effect for the past several years. (Tr. 205:20-23.) Dr. Grabowski also disagreed with Dr. McDuff about the role of marketing efforts and conversion strategy: there’s no evidence that Sanofi did excessive marketing for this product. (Tr. 205:24-206:11.)

On cross-examination, Dr. Grabowski agreed that, by 2004, Lantus could be considered a blockbuster drug. (Tr. 207:14-19.) The DCA press release does not constitute industry praise.

(Tr. 211:16-19.) The article Dr. Grabowski cited about superior injection force was authored by Sanofi. (Tr. 214:11-14.) In 2007, there were 30 pages of winners of the Good Design Award, with 16 other recipients in the medical category. (Tr. 217:14-23.)

E. Testimony of Michael Quinn

What follows is a summary of the witness's testimony. Mr. Quinn is a mechanical engineer who designed the BD Vystra[2] pen, which is Mylan's proposed product. (Tr. 222:12-25.) Mr. Quinn was admitted as an expert in the field of mechanical engineering, mechanisms, and mechanical systems, including medical devices, medical injector pen, and medical device design, development, and manufacturing. (Tr. 226:1-6.)

In the '844 pen, the clutch and dial sleeve are connected to each other, and during dialing the clutch and drive sleeve rotate. (Tr. 228:20-22.) In Mylan's pen, the dose set knob and the setback are not connected, and as a user would dial or dial back, the setback and lead screw don't rotate relative to the rest of the pen. (Tr. 228:23-229:1.) The opposite are the case during dose administration. (Tr. 229:2-10.)

As to the "releasably connected" limitation in claim 21, the word "connected" implies that the components in a nominal state are joined to each other; the word is not "connectable," but "connected." (Tr. 235:20-236:2.) The '844 patent specification discloses that the clutch and the dial sleeve are spring-loaded to be connected in a nominal state as well as dialing and dial back. (Tr. 236:6-9.) The Vystra pen does not meet the "releasably connected" limitation in claim 1. (Tr. 238:7-11.)

[2] It appears that "Semglee" and "Vystra" are different names for the same thing, Mylan's accused pen product. (See Tr. 249:3-9.)

As to the limitation in claim 21 that requires a piston rod holder configured to prevent rotation during dose setting, the Vystra pen does not have this element. (Tr. 238:16-20.) Dr. Reinholtz testified that the brake tower was the piston rod element, but his report said that it was the tower core alone or in conjunction with the brake tower. (Tr. 238:21-239:5.) Mr. Quinn disagreed with Dr. Reinholtz, because the plunger rod has no torque applied to it from the pen during dose dialing, so nothing is needed to prevent its rotation. (Tr. 239:6-11.) The plunger rod doesn't receive any torque because the setback absorbs it all and prevents any further motion during dialing. (Tr. 239:13-15.) Because the setback isn't rotating during dose setting, nothing inside of it is rotating during dose setting, including the lead screw and including the plunger rod. (Tr. 240:5-7.) The tower core in Vystra is not configured to prevent rotation, but instead has two main functions. (Tr. 240:8-10.) The first is to hold the lead screw and keep it from popping out the back of the pen. (Tr. 240:11-13.) The second is to prevent the plunger rod from rotating during dose injection because it's during dose injection that the lead screw is turning, and that's when torque is applied to the plunger rod. (Tr. 240:17-20.) The components in the Vystra are not configured as the claim language requires. (Tr. 241:4-14.)

Dr. Reinholtz' experiment on the Vystra did not accurately represent the pen. (Tr. 241:20-24.) In addition to removing the tower core, Dr. Reinholtz also removed the dose stop, and he also pre-advanced the stopper in the cartridge. (Tr. 242:1-3.) He loosened up the setback, which allows the lead screw to have more play, and he removed the tower core, which supports the shaft of the lead screw, allowing the lead screw more freedom to move around. (Tr. 242:6-11.) Most importantly, he pre-advanced the stopper away from the pressure foot of the plunger rod; all these changes made a very loose system of parts. (Tr. 242:12-14.) The

experiment does not prove that the tower core is configured to prevent rotation during dialing. (Tr. 242:19-20.) Dr. Reinholtz removed constraints in the pen with the effect of allowing more vibration. (Tr. 242:22-23.) He eliminated a key constraint on the plunger rod, its contact with the rubber stopper in the cartridge holder. (Tr. 242:23-25.) By aiming the pen upward and using dialing to create vibration, he got the plunger rod to rotate itself back down on the lead screw. (Tr. 243:1-5.) He also admitted that, if he points the needle end down and the pressure foot of the plunger rod touches the stopper, if dialed, the plunger rod does not rotate. (Tr. 243:5-8.) The experiment is not something a person of ordinary skill in the art (hereinafter, "POSA") would consider in evaluating a pen injector. (Tr. 243:12-17.) Vystra does not meet the limitations of claim 21. (Tr. 243:21-22.)

Vystra does not meet the limitations of claim 25 because claim 25 depends on claim 23, which requires a clutch, which Vystra does not have. (Tr. 244:4-9.) According to Dr. Reinholtz, the sleeve of claim 21 is the setback of the Vystra, so there's no component left to be the clutch. (Tr. 244:12-245:2.) If one allows one component to have two functions, the setback could have a clutch function: a series of four nubs interact with the dose set knob on injection, and those are the clutch elements. (Tr. 245:16-21.) The setback has a lot of functions besides the clutching function; there are internally facing click teeth, but these have nothing to do with clutching. (Tr. 245:24-246:5.) The audible clicks do not come from the clutching aspect of the setback. (Tr. 246:8-9.) Vystra does not meet the limitations of claim 25. (Tr. 246:10-13.)

As to the nut limitation in claim 30, a POSA would understand a nut as a mechanical component containing internal threads and some form of features on the outside for fixation or

connection using tools. (Tr. 246:21-25.) The '844 specification, at col.4 ll.26-35, describes the nut as having internal threads and external teeth, which interact with the housing to prevent rotation. (Tr. 247:1-7.) Dr. Reinholtz contends that the Vystra dose stop is a nut; it has external threads and a smooth inside surface. (Tr. 247:13-20.) A pipe nipple is not a nut. (Tr. 248:2-7.) The Vystra does not meet the limitations of claim 30. (Tr. 248:8-11.)

On cross-examination, Mr. Quinn said that, while the claim did not use language requiring a releasable connection in the resting state, that is implied by the ordinary meaning of "connected." (Tr. 251:23-252:3.) In the Vystra, the tower core holds the piston rod and prevents rotation during injection. (Tr. 252:13-17.) Mr. Quinn stated that he had a patent application related to Vystra, and the tower core and the piston rod in that application correspond to what is in the Vystra. (Tr. 253:5-25.) This application states: "The brake tower core 220 functions to prevent rotation of the piston rod 206 relative to the brake tower 205 and thus the pen upper body 201." (Tr. 254:2-7.) The keyed engagement between the tower core and the piston rod functions to prevent rotation between them. (Tr. 254:13-19.) The keyed connection always exists. (Tr. 254:20-24.)

The Vystra setback is both a sleeve and a clutch. (Tr. 258:11-12.) In the patent application related to the Vystra, the dose stop member is described as a half nut-like element. (Tr. 259:21-260:13.) Mr. Quinn agreed that he is a named inventor on U.S. Patent No. 9,757,525. (Tr. 261:3-6.) Figure 16a in that patent shows a threaded piston rod with a circular cross-section. (Tr. 261:18-25.)

On redirect examination, Mr. Quinn said that the Vystra tower core prevented rotation on dose administration, but Vystra is not configured to prevent rotation during dose setting. (Tr.

263:3-11.) As to DDX-209, the image shows two different sets of teeth; the teeth with a red and yellow outline are the teeth that result in the clicking, and these are different from the setback clutch teeth which are shown in blue. (Tr. 263:12-264:1.) The phrase "half nut-like" is not equivalent to "half nut;" what is "half nut-like" is not a "half nut." (Tr. 264:8-17.)

F. Testimony of Karl Leinsing

What follows is a summary of the witness's testimony. Mr. Leinsing was admitted as an expert in mechanical engineering, mechanisms for medical systems, full life cycle product development of medical devices from conception to manufacturing, drug and delivery medical devices such as auto injectors, pen injectors, and pumps. (Tr. 277:10-17.) Mr. Leinsing said that, for his analysis in this case, he used March 3, 2003, the date of filing of a foreign priority application, as the priority date. (Tr. 279:12-22.)

Mr. Leinsing said that the claims at issue lack written description and enablement. (Tr. 280:16-19.) The claims of the '844 patent refer to an internally threaded piston rod, but the specification does not describe or show one. (Tr. 283:24-284:4.) Figure 1 of the '844 patent teaches only a piston rod with two opposing threads on the outside of the piston rod; there is no mechanism with threads on the inside. (Tr. 284:20-285:7.) Claim 21 discloses a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread, but nothing in the specification mentions anything about internal threads on the piston rod. (Tr. 285:11-22.) Given this, it would have been very difficult for a POSA at the time to design and implement an internally threaded piston rod; it would have required a lot of changes. (Tr. 285:23-286:2.) There's no prior art that shows a pen injector with threads on the inside of a piston rod, and a POSA would not have understood. (Tr. 286:2-8.) As to the sketch that Dr.

Slocum made at his deposition, the sketch shows that a lot of detail is required, and it creates structural problems and manufacturing problems. (Tr. 286:17-287:5.) Also, the '844 patent has discussions of the drive sleeve needing to be between the dose setting sleeve and the piston rod, and that's not possible with this configuration. (Tr. 287:7-11.) Dr. Slocum's sketch shows a tiny threaded rod that goes inside the piston rod, which he calls a stinger, but it would have to be extremely small and would likely buckle, forcing the whole device to be made much bigger. (Tr. 287:22-288:4.) Mr. Leinsing did not know of anything that would fit inside the hole in the piston rod, and it's not something that's been ever been done in a pen injector. (Tr. 289:1-9) Dr. Slocum's proposed design also requires an additional part and a bond, plus the small threaded rod would have to be aligned with an outer sleeve, which would add complexity and require time and experimentation to figure out; it would not be easy. (Tr. 289:15-25.) Mr. Leinsing did not believe that the inventors possessed an internally threaded piston rod. (Tr. 290:4-7.)

The claim speaks of a "drive member," and, when you look at the specification, the only thing that could be is a sleeve, and the specification says that the drive sleeve is located between the dose dial sleeve and the piston rod. (Tr. 290:12-17.) So Dr. Slocum's proposal conflicts with the specification, because that would mean the drive member would not be between the piston rod and the dose dial sleeve; instead, the piston rod would be between a drive rod and a dose setting sleeve. (Tr. 290:17-23.) Dr. Slocum's proposal would be a different device altogether, and it would take at least a year of experimentation to make it all work. (Tr. 291:3-7.) Dr. Slocum's proposal would require making the entire device bigger, which is problematic, because we want these devices to be small enough to hold in one's hand. (Tr. 291:23-292:4.)

Claim 21 requires a piston rod holder that is rotatably fixed relative to the housing, so it's fixed to the outer housing of the pen injector, and configured to prevent the piston rod from rotating during dose setting, and to permit the piston rod to traverse axially toward the distal end during dispensing. (Tr. 293:7-12.) The word "holder" does not appear in the specification, and the closest thing Mr. Leinsing could find was insert 16, which is like a washer with threads on the inside. (Tr. 293:16-24.) In other places in the specification, it says that the threads on the inside of this insert work with the opposing threads of the piston rod to prevent rotation, so the insert 16 does not prevent rotation all on its own. (Tr. 293:25-294:4.) The insert 16 is not a holder and not labeled as a holder. (Tr. 294:11-13.) A POSA would not have thought that the inventors had possession of the claimed piston rod holder as of the priority date. (Tr. 294:14-17.)

Four elements in claim 21 are at issue in this trial: 1) a driving member comprising a third thread; 2) a piston rod comprising either an internal or an external fourth thread that is engaged with a third thread; 3) the driving member is configured to rotate relative to the piston rod; and 4) the piston rod and the driving member are configured to rotate relative to one another during dose dispensing, and the piston rod is configured to traverse axially towards the dose dispensing and during dose dispensing [*sic*]. (Tr. 295:22-296:12.) These four elements are all related to the concept of having a driver with threads within it and a nut member that would have a through slot or a guide. (Tr. 296:13-17.) The Steenfeldt-Jensen patent (hereinafter, "SJP") has five embodiments, and the fifth embodiment, in figures 15 through 17, is of particular interest. (Tr. 297:2-8.) SJP has certain teachings about the way in which the driver, the piston rod, and the nut member work together. (Tr. 299:4-10.) Inside the driver, there is a slotted

guide. (Tr. 300:4-6.) SJP teaches that you can exchange the threads in the nut member and the slot in the driver: you can put the threads in the driver and the slot into the nut. (Tr. 300:15-19.) SJP teaches that these are alternative design choices: you can put the threads on the nut member or you can put the threads on the driver and put the slotted guide on the nut member or on the driver. (Tr. 301:7-11.) It doesn't matter which alternative you pick; you get the same action on the piston rod. (Tr. 301:11-13.) SJP encourages switching the slot and the threads. (Tr. 302:18-22.) Swapping the threads and the slot can eliminate the need for a thrust washer, and eliminating a component helps reduce cost. (Tr. 305:4-13.) Claims 1 and 6 in the '844 patent show the same idea, swapping the threads and the slot. (Tr. 305:20-306:5.) This swap is very simple and has been done in other pieces of prior art, Giambattista and Chanoch. (Tr. 306:22-25.)

Mr. Leinsing did not agree with Dr. Slocum that such a change would increase the injection force by about 50%. (Tr. 307:14-20.) The change would result in the piston rod no longer turning, which would reduce the friction, and Dr. Slocum did not account for that. (Tr. 308:8-19.) Mr. Leinsing did not agree with the value of the coefficient of friction Dr. Slocum used in his calculations, .15; using lubricants can bring the value down to .05, and Dr. Slocum said that some plastics could produce a value of .08, which would reduce the 51% figure he computed. (Tr. 309:3-7.) Dr. Slocum should have used .05. (Tr. 309:8-11.) Dr. Slocum also didn't take into account the pressure foot, as well as changes that you can make with the thrust bearing. (Tr. 309:23-25.) Had he chosen a smaller size for the thrust bearing, that would have reduced the friction. (Tr. 310:1-3.)

Mr. Leinsing said that the Chanoch patent confirmed the interchangeability of slots and

threads. (Tr. 310:6-13.) A POSA swapping slots and threads in SJP embodiment 5 would have a reasonable expectation of success. (Tr. 311:16-20.)

Claim 22 requires a piston rod with a circular cross-section. (Tr. 312:9-11.) The specification refers to a piston rod that is generally circular in cross-section. (Tr. 312:12-20.) When you look at the actual piston rod, it has threads and flats on it, as well as other parts that don't make it circular, so it is described as generally circular. (Tr. 312:22-25.) The original British patent application shows a piston rod with threads on both ends; a cross-section of either threaded section is not circular. (Tr. 313:1-25.) It also has little holes in it that prevent it from being perfectly circular, and that's why it is described as generally circular. (Tr. 314:1-3.) A threaded rod does not have a perfectly circular cross-section. (Tr. 314:13-16.) It's not appropriate to ignore the threads when considering the shape of the cross-section. (Tr. 314:17-20.) SJP discloses a piston rod with a circular cross-section. (Tr. 314:21-24.) Mr. Leinsing did not agree with Dr. Slocum that claim 22 requires a circular section along the entire length of the piston rod. (Tr. 315:10-17.) Claim 22 does not specify the entire length of the piston rod. (Tr. 315:19-21.) Claim 22 is obvious over SJP in view of Chanoch because those references disclose piston rods with circular cross-sections. (Tr. 316:5-10.)

As to claim 30, disclosing a nut that tracks each set dose of medicament delivered, prior art would teach a POSA that dose tracking is important. (316:13-18.) ISO standard 11608-1, from the year 2000, sets requirements for pen injectors, including, "does not allow a larger dose to be preset than is left in the cartridge." (Tr. 316:22-317:9.) A POSA would understand from this that they need to track the amount of medication that's in the cartridge, which was commonly done in 2003 with a nut member that tracked over threads. (Tr. 317:14-22.) A

DCA document on the FlexPen shows a small nut member that rides over threads which correspond to the amount of medication that's in the vial. (Tr. 318:3-16.) The nut moves to track the amount remaining and, when it gets to the very end, the medication remaining is zero, and the device cannot rotate anymore. (Tr. 318:17-21.) Figure 3 of the Klitgaard reference shows the same thing, and a POSA would have known how to use a nut to track the amount of remaining medication in an injector pen. (Tr. 319:2-22.) Claim 30 would be obvious over SJP in view of Chanoch. (Tr. 320:1-4.)

SJP and the FlexPen are very similar, but FlexPen also has a nut member to track the medication left in the vial. (Tr. 320:10-17.) DDX-331 shows that SJP and FlexPen have all the same components, with small changes, and the addition of this limiting nut. (Tr. 320:18-25.) Because SJP and FlexPen have the same components, the analysis is the same. (Tr. 321:1-3.) Mr. Leinsing had held a FlexPen in his hands before 2003, in 2002. (Tr. 323:3-19.) Claim 21 is obvious over the FlexPen. (Tr. 323:24-324:1.) Claim 22 has the same analysis for FlexPen as for SJP; FlexPen has areas of circular cross-sections. (Tr. 324:5-8.)

The Giambattista Patent (hereinafter, "GiaP"), from June of 2001, teaches a piston rod holder meeting the limitations of claim 21. (Tr. 325:4-11.) In figure 4, there's an element with a guided slot and with teeth; when assembled, those teeth line up with other teeth to prevent rotation, and it is the piston rod holder. (Tr. 325:16-24.) Figure 9 shows a piston rod with a generally circular cross-section, so it would meet the limitations of claim 22. (Tr. 326:5-14.)

On cross-examination, Mr. Leinsing said that, with a few changes, the FlexPen is essentially the fifth embodiment of SJP ("SJP5.") (Tr. 328:7-18.) The key element that is not in SJP is the dose limiting nut. (Tr. 328:21-329:1.) Both FlexPen and SJP5 have a piston rod,

a driver tube, and a nut, and the piston rod's threads mate with the nut's threads; we can swap the driver tube slot with the threads on the nut. (Tr. 336:5-337:1.) FlexPen had a high injection force relative to some other pens. (Tr. 338:8-14.) In designing the Next Generation FlexPen, Novo reduced the injection force of the FlexPen. (Tr. 338:14-340:14.) At his deposition, Mr. Leising had opined that the swap of slot and threads would be "essentially a wash" as to injection force, but his expert report had no force calculations. (Tr. 341:8-24.) Based on the calculations he performed but did not report, he stated at his deposition that the swap would produce a 25 to 30% increase in injection force, but that did not include the correction of the thrust washer. (Tr. 341:23-342:19.) Claims 1 and 6 of SJP require a piston rod having a not circular cross-section. (Tr. 343:3-16.) SJP repeatedly describes the piston rod as having a noncircular cross-section, but the figures plainly show other sections of the piston rod that are circular, even though SJP never refers to the piston rod as having a circular cross-section. (Tr. 343:18-344:16.) Mr. Leinsing believes that the SJP piston rod has a circular cross-section because portions at either end have such. (Tr. 344:17-23.) On one end is an interface to the bearing, on the other end is a circular flange, and in the middle is the threaded part of the rod; there is a part with a circular cross-section and a part with a noncircular cross-section. (Tr. 345:14-25.)

As to GiaP, Mr. Leinsing opined that retract nut 4 is the claimed piston rod holder. (Tr. 346:1-6.) The retract nut is designed so that it can be rotated with respect to the housing when you disassemble the pen, but not in normal operation. (Tr. 346:11-19.) The insert 16 in the '844 patent cannot be rotated out of the housing, but it's still a piston rod holder. (Tr. 347:1-13.)

Mr. Leinsing agreed that he opined that use of an internally threaded piston rod would

require enlarging the entire device but did no calculations to support that. (Tr. 353:5-17.)

On redirect examination, Mr. Leinsing stated that the GiaP pen is reusable, and the holder that is rotatably fixed during injection permits rotation during cartridge reloading. (Tr. 359:1-11.)

G. Testimony of William Biggs

What follows is a summary of the witness's testimony. Dr. Biggs was admitted as an expert in endocrinology and in the treatment of patients with diabetes. (Tr. 369:18-22.) He began prescribing Lantus® insulin in vials in 2001 and it was far superior to existing long-acting insulins. (Tr. 372:1-7.) Existing injector pens were easy to use. (Tr. 373:15-16.) Lantus® insulin was available in the OptiClik pen prior to SoloSTAR®, but the OptiClik was defective and unreliable in giving the correct dose. (Tr. 374:2-4.) Dr. Biggs has never had any problems or complaints from patients about injection force. (Tr. 375:18-21.) A patient can use less force in injection and it just makes the insulin go in a little slower. (Tr. 376:16-20.) Injection force has never prevented any of Dr. Bigg's patients from using an injection pen. (Tr. 376:23-24.) If a patient can't use one brand of pen, it would be foolish and hazardous to try to use another, because they are not that significantly different. (Tr. 377:13-15.) Multiple pens prior to SoloSTAR®, including OptiClik, had a capacity of 80 units. (Tr. 378:3-7.) The advantages that Dr. Goland stated were unique to SoloSTAR® are shared among other pens and were available in other pens before SoloSTAR®. (Tr. 379:7-12.) SoloSTAR® is a fine pen, but it's not special. (Tr. 380:1-4.) The FlexPen worked fine and Dr. Biggs never had a reason to change a patient from FlexPen. (Tr. 381:2-9.) Lantus SoloSTAR® did not satisfy any long-felt unmet need. (Tr. 382:7-9.)

On cross-examination, Dr. Biggs stated that he had patients with hand dexterity problems and other difficulties with the use of their hands. (Tr. 386:19-387:11.)

H. Testimony of Robert McDuff

What follows is a summary of the witness's testimony. Dr. McDuff was admitted as an expert in the area of economics, including health and pharmaceutical economics. (Tr. 404:17-19.) Dr. McDuff, in summary, concluded that Dr Grabowski's economic analysis was flawed, that there was no nexus to the '844 patent, and that the effect of blocking patents makes commercial success irrelevant. (Tr. 405:23-406:3.) Sanofi's own analysis showed that the increment that came from SoloSTAR® was small relative to overall Lantus® use, and SoloSTAR® had a relatively modest impact on the overall performance of the group of products. (Tr. 410:1-14.)

The available data shows that, contrary to what Dr. Grabowski stated, Lantus® prescriptions did not accelerate after the introduction of SoloSTAR®; there is no observable change. (Tr. 410:21-411:7.) To the contrary, after the introduction of SoloSTAR®, the prescription growth rate diminished. (Tr. 411:10-16.)

Dr. McDuff said that there was a very weak connection between the '844 patent and any commercial success. (Tr. 412:5-7.) The Lantus® products were covered by 22 patents listed by Sanofi in the Orange Book. (Tr. 412:19-22.) If one does not consider all of the relevant patents, you might misattribute sales to one patent because you haven't looked at the others. (Tr. 413:2-6.)

Exhibit DTX-2634 is Sanofi document related to a third-party analysis conducted by Compass which identifies the most important attributes for SoloSTAR®, and the most important

attributes are properties of the insulin, not the pen. (Tr. 414:17-415:7.) A 2011 analysis of SoloSTAR® injection force shows the same thing, that the pen is of secondary importance relative to the insulin. (Tr. 416:3-12.) A Sanofi document ranked pen attributes, and injection force was the eighth most important attribute out of 13. (Tr. 416:13-417:2.) The sales of SoloSTAR® were driven by the properties of the insulin, not the pen. (Tr. 417:9-14.) Lantus SoloSTAR® sales declined with the launch of the Basaglar KwikPen, which also uses insulin glargine like Lantus®. (Tr. 418:1-7.) And, while it is true that SoloSTAR® won some awards, those awards are for the pen and do not focus on the benefits of the '844 patent. (Tr. 419:14-19.)

Dr. McDuff used the wrong time period in his blocking analysis, pointing to the expiration of patents in 2014. (Tr. 420:6-13.) The relevant time period is that leading up to the priority date in 2003. (Tr. 420:15-17.)

Analysis of market share of the various Lantus® and SoloSTAR® products shows that the primary commercial opportunity was the opportunity to sell insulin glargine, which was protected by the blocking insulin glargine patents. (Tr. 423:23-424:11.) "The big difference between the insulin glargine SoloSTAR® products and the other insulins shows that it's the insulin not the SoloSTAR® that's driving sales." (Tr. 424:13-15.) The blocking patents provided strong disincentives to develop products sooner, so there is no inference to be made about the obviousness of the '844 patent. (Tr. 424:18-21.)

On cross-examination, Dr. McDuff agreed that the Design Business Association press release about the award it gave SoloSTAR® in 2009 mentioned low injection force. (Tr. 430:10-17.) Dr. McDuff agreed that, comparing the prescriptions for OptiClik and SoloSTAR®

in the first four years of each, shows that SoloSTAR® achieved quadruple the amount that OptiClik did. (Tr. 431:17-432:1.)

I. Testimony of Alexander Slocum

What follows is a summary of the witness's testimony. Dr. Slocum was admitted as an expert in the field of mechanical engineering, mechanisms and mechanical systems, including medical devices. (Tr. 444:16-20.) Dr. Slocum stated that the FlexPen corresponds to the fifth embodiment of SJP ("SJP5"), and there is no meaningful difference for the purpose of the analysis of claim 21. (Tr. 451:17-20.) Mr. Leinsing had characterized the modifications to SJP5, which result in the device of claim 21, as a simple substitution, but it is not. (Tr. 455:24-456:2.) These modifications change the physics of operation, or the force loop, and actually increase the injection force needed. (Tr. 456:3-10.) These modifications introduce a rotating element after the nut thread that produces a lot of drag. (Tr. 459:11-14.) The result is that the device becomes less efficient, and you have a higher injection force, which would increase significantly. (Tr. 460:21-461:3.) The POSA would not be motivated to make this modification because one goal of the patent was to lower injection force. (Tr. 461:4-9.) The proposed modification of the FlexPen would increase injection force by about 50%. (Tr. 462:2-6.)

Dr. Slocum stated that his analysis of injection force used as inputs measurements of the FlexPen done by Mr. Veasey, as well as Mr. Veasey's measurement of the coefficient of friction between the plastic elements. (Tr. 462:7-13.) Mr. Veasey gave Dr. Slocum a value of .1 for the coefficient of friction, which is what Dr. Slocum used. (Tr. 462:24-463:2.) Mr. Veasey's actual measurement of the coefficient of friction in the FlexPen was .15, but Dr. Slocum knew

from his own experience that .1 was a very good value. (Tr. 463:5-10.) Dr. Slocum did not agree with Mr. Leinsing that one could use a value of .05. (Tr. 463:11-14.) But using a lower coefficient of friction would still result in an increase in injection force of about 30%; the increase will not go to zero. (Tr. 465:17-19.)

Dr. Slocum described an article he reviewed about the modifications to the FlexPen which produced the Next Generation FlexPen; the article reported a 30% reduction in injection force. (Tr. 472:5-473:4.)

Dr. Slocum did not agree that the specification of SJP suggests swapping the driver tube and the threads in SJP5. (Tr. 473:22-474:4.) The first and fifth embodiments in SJP are very different. (Tr. 475:5-7.)

Dr. Slocum did not agree that the pressure foot, which Mr. Leinsing called a "thrust washer," could be eliminated. (Tr. 483:19-484:2.) As to Chanoch, which uses a threaded driver tube, using a threaded driver tube with SJP5 would increase the injection force required. (Tr. 484:13-24.)

GiaP lacks a piston rod holder rotatably fixed to the housing. (Tr. 485:10-13.) Dr. Slocum disagreed with Mr. Leinsing that the GiaP retract nut 4 is a piston rod holder rotatably fixed to the housing. (Tr. 485:21-486:2.) GiaP discloses a reusable pen injector; when one exchanges the vial, the retract nut disengages and freely rotates, so it is not fixed to the housing. (Tr. 486:2-19.)

As to the requirement in claim 22 of a piston rod with a circular cross-section, SJP5 does not have one, nor does FlexPen, nor does GiaP. (Tr. 487:1-12.) The piston rod in figure 17 of SJP has a rather rectangular cross-section. (Tr. 487:14-25.) The abstract of SJP refers to a

piston rod with a non-circular cross-section. (Tr. 488:2-9.) Because of the non-circular cross-section, the driver tube and piston rod in SJP always rotate together. (Tr. 488:20-23.) The piston rod of the FlexPen is very similar to SJP, a cross-section like a rectangle with rounded ends. (Tr. 489:10-17.) GiaP also has a piston rod with flat sides. (Tr. 490:3-6.) Dr. Slocum did not agree with Mr. Leinsing that the SJP piston rod has a circular cross-section based on the ends, because the ends of a lead screw are not doing the screwing; they are called end journals. (Tr. 490:20-491:5.) The end journals of lead screws can have many different shapes; it is the threaded part of the lead screw that does the work of providing the axial force, so that's where you look at the cross-section. (Tr. 491:6-13.) Dr. Slocum also did not agree that the piston rod in the '844 patent has a non-circular cross-section because it has threads; a POSA would ignore the thread in assessing the cross-section of the rod. (Tr. 491:19-492:9.)

As to the issue surrounding the piston rod comprising an internal third thread, Dr. Slocum stated that he believed that these limitations had written description support and are enabled. (Tr. 492:21-493:8.) External and internal thread are alternative terms for male and female thread, respectively. (Tr. 493:9-12.) In Figure 1 of the '844 patent, the piston rod has external threads and the drive sleeve has internal threads. (Tr. 493:17-494:1.) There are two possible arrangements for the threading of a piston rod threaded to a driver: internal/external and external/internal. (Tr. 495:13-17.) The specification, in columns 1 and 2, does not yet choose one arrangement of the two. (Tr. 494:6-495:12.) The Great Britain application gives an example of a leadscrew drive system, a concept that is centuries old. (Tr. 496:5-497:4.) Dr. Slocum said that he wrote a textbook in 1995 that taught the principles of a leadscrew drive system with a leadscrew and nut, which produce relative rotation between leadscrew and nut.

(Tr. 497:8-498:4.) A POSA would understand that a piston rod threaded to a driver is a leadscrew system. (Tr. 498:5-7.) In 2003, it was known in the art that a piston rod can have internal threads, engaged with a driver having external threads. (Tr. 498:22-25.) The '872 patent, from 1987, discloses an insulin pump with an internally threaded piston member, which advances the piston. (Tr. 499:4-24.) The '824 patent, from 1988, discloses an injection device with an internally threaded piston rod which receives a drive screw. (Tr. 500:2-18.)

Dr. Slocum drew a diagram at his IPR deposition to depict the two possible threading arrangements. (Tr. 501:4-14.) The drawing shows the arrangement of the dose dial sleeve, the tubular clutch, the drive sleeve, and the piston rod. (Tr. 502:1-21.) At one end of the piston rod are the labels, "first thread" and "external." (Tr. 502:21-23.) At the other end, it just says, "thread?" and the drawing depicts internal threading there. (Tr. 502:23-503:3.) The drive sleeve is a relatively long, thin threaded piece labeled a "stinger." (Tr. 503:4-25.) This diagram relies only on the patent and the background knowledge of a POSA. (Tr. 504:1-4.) A POSA who read the '844 patent and had the knowledge of the art about leadscrew drive systems could envision arrangements in which a piston rod with an internal thread is engaged with a driver having an external thread. (Tr. 504:5-11.) Dr. Slocum did not agree with Mr. Leinsing that this arrangement requires that the entire device be bigger, nor that there would be manufacturing problems with bonding inside the drive sleeve, nor that the size of the driver would result in buckling. (Tr. 504:12-506:21.) The patent disclosure enables the POSA to practice the pen injector having a piston rod with either internal or external threads, without undue experimentation. (Tr. 506:24-507:8.) It might take a POSA a month to make. (Tr. 507:9-12.) This modification differs from the question of switching the slot and the threads in SJP, which

fundamentally changes the physics of operation of the device. (Tr. 509:21-511:18.)

As to the piston rod holder, the '844 specification depicts insert 16. (Tr. 512:2-10.) The insert 16 is secured against rotation and has a threaded opening through which the piston rod extends, and the opposing thread directions prevent piston rod rotation. (Tr. 512:17-24.) Removal of the insert allows the piston rod to rotate. (Tr. 514:21-515:7.) The insert is also configured to permit the piston rod to traverse axially toward the dose dispensing end, because if one rotates the drive sleeve, it moves relative to the insert and the piston rod rotates with the threads engaged and it advances. (Tr. 515:17-22.) There is written description support for the piston rod holder limitation, and the patent teaches a POSA to make and use the piston rod holder without undue experimentation. (Tr. 515:23-516:4.)

SoloSTAR® practices claims 21, 25, and 30 of the '844 patent. (Tr. 516:11-13.) Two pieces of the SoloSTAR®, snapped together, form the housing. (Tr. 517:9-20.) The claimed invention provides benefits of high efficiency, requiring less thumb force for injection, and a lower component count. (Tr. 518:1-25.)

On cross-examination, Dr. Slocum said that, as of March, 2003, he had no personal experience designing injector pens. (Tr. 519:17-19.) The first declaration he filed when retained by Sanofi for the IPR contained an error. (Tr. 520:8-24.) Dr. Slocum agreed that he had relied on information about injection pens provided by Mr. Veasey. (Tr. 522:5-524:18.) Dr. Slocum disagreed with Mr. Leinsing that a POSA would have swapped the slot and the threads. (Tr. 525:3-13.) Dr. Slocum thought that the passage in SJP that talks about the swap would be ignored by a POSA who would think that it is a stupid idea and would ignore it. (Tr. 525:14-529:12.) Nonetheless, Dr. Slocum agreed that that particular passage in SJP does

envision swapping the slot and the thread. (Tr. 530:2-10.) As to the first embodiment in SJP, a POSA could accomplish that swap. (Tr. 530:12-15.) While embodiments one and five in SJP are very different, they are very similar in terms of dispensing and the force chain for dispensing. (Tr. 531:2-22.)

The piston rod in SJP claim 6 corresponds to the piston rod threading limitation in '844 patent claim 21. (Tr. 536:8-24.) The piston rod drive in SJP claim 6 meets the claim 21 limitation of a driving member comprising a third thread. (Tr. 538:13-23.) SJP claim 6 also meets the claim 21 limitation of a driving member configured to rotate relative to the piston. (Tr. 539:20-540:15.) SJP claim 6 also meets the claim 21 limitation about the configuration of the piston rod and the driving member during dose dispensing. (Tr. 540:19-541:11.) Dr. Slocum agreed that SJP claim 6 meets all four of the claim 21 limitations that the parties did not stipulate to. (Tr. 542:13-24.)

Dr. Slocum did his injection force analysis on an Excel spreadsheet. (Tr. 544:3-5.) Many of the inputs were values that Mr. Veasey gave Dr. Slocum. (Tr. 546:11-17.) The coefficient of friction value of .1 came from Mr. Veasey. (Tr. 553:24-25.) Lubricious plastics can get down to values of .08 or lower in some instruments. (Tr. 554:14-18.) While Mr. Veasey measured a value of .15, he recommended a value of .1, which Dr. Slocum used. (Tr. 555:2-7.) The 51% value is the ratio of the force outputs for the devices compared. (Tr. 557:1-6.) Dr. Slocum had written in a book that sliding contact bearings have a coefficient of friction on the order of .05 to .1. (Tr. 558:8-559:2.) The exact value depends on what plastic you use. (Tr. 559:8-13.) A change in the outside and inside diameter values used would change the 51% value. (Tr. 559:24-560:5.) The spreadsheet does not account for certain lost friction force.

(Tr. 562:20-24.)

As to GiaP, when the pen is operational, the retract nut is rotatably fixed relative to the housing. (Tr. 565:3-11.)

SJP figure 8 shows a piston rod with an end journal with a circular cross-section. (Tr. 575:18-576:3.) One can change the spreadsheet analysis to reflect a stinger design and it shows that the stinger will not buckle. (Tr. 580:6-585:4.) The Camen patent and the Spinello reference do not deal with injector pens, and both designs have motors. (Tr. 586:8-587:1.) The claims of the '844 patent do not require low injection force, or shorter dial extension and increased maximum dose. (Tr. 593:11-22.)

On redirect examination, Dr. Slocum said that SJP claim 6 does not have a housing with a thread, nor a dose indicator with a second thread that engages the housing thread, nor a releasably connected sleeve. (Tr. 597:6-598:3.) In order to find every element of claim 21 in SJP, one must mix and match between SJP embodiments and make changes to SJP5. (Tr. 598:10-14.) Even if Dr. Slocum had used a value for the coefficient of friction of .05 in his spreadsheet, the required injection force, comparing SJP5 with modified SJP5, would still increase. (Tr. 598:20-25.) Dr. Slocum used a value of .1, even though Mr. Veasey had measured a value of .15, because Mr. Veasey said the use of lubricious plastics maybe could result in a value of .1. (Tr. 599:8-13.)

DISCUSSION

Sanofi contends that the Vystra would infringe claims 21, 22, 25, and 30 of the '844 patent. These claims, together with intervening dependent claims, are as follows:

> 21. A drug delivery device comprising: a housing comprising a dose dispensing end and a first thread; a dose indicator comprising a second thread that engages

with the first thread; a driving member comprising a third thread; a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator; a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread; a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the distal end during dose dispensing; wherein: the housing is disposed at an outermost position of the drug delivery device; the dose indicator is disposed between the housing and the sleeve and is configured to (i) rotate and traverse axially away from the dose dispensing end during dose setting and (ii) rotate and traverse axially towards the dose dispensing end during dose dispensing; the driving member is configured to rotate relative to the piston rod; the sleeve is rotatably fixed relative to the driving member and configured to traverse axially with the dose indicator; and the piston rod and the driving member are configured to rotate relative to one another during dose dispensing; and the piston rod is configured to traverse axially towards the dose dispensing end during dose dispensing.

22. The drug delivery device of claim 21 where the piston rod has a circular cross-section.

23. The drug delivery device of claim 21 further comprising a clutch.

24. The drug delivery device of claim 23 where the clutch provides audible and tactile feedback indicative of unit doses of medicament.

25. The drug delivery device of claim 24 where the clutch provides audible clicks during dose cancelling, where each click is equal to a unit dose of medicament.

30. The drug delivery device of claim 21 further comprises a nut that tracks each set dose of medicament delivered.

A. Infringement

The parties entered into a key stipulation on November 29, 2019, regarding claim elements contained in the Vystra and in certain prior art references (hereinafter, the "Element Stipulation"), signed and filed by the Court on December 2, 2019. In the Element Stipulation, the parties agreed that the Vystra meets every limitation of claim 21, with the exception of the following:

> and (ii) releasably connected to the dose indicator; a piston rod comprising either an internal or an external fourth thread that is engaged with the third thread; a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the distal end during dose dispensing;

(Element Stipulation at 2-3.) This streamlines the claim 21 infringement inquiry at trial and limits it to three principal elements: 1) a sleeve releasably connected to the dose indicator; 2) the piston rod, with its internal or external thread; and 3) the piston rod holder, with its configuration relative to the piston rod. In its post-trial brief ("PTB"), Sanofi asserts that Vystra meets these three limitation elements. In its PTB, Mylan disputes that Vystra contains a releasably connected sleeve or the piston rod holder. Thus, Mylan does not dispute Sanofi's contention that Vystra meets the piston rod limitation ("a piston rod comprising . . . third thread").

1. Infringement of claim 21: "releasably connected"

Claim 21 contains these limitations:

> a sleeve that is (i) disposed between the dose indicator and the driving member and (ii) releasably connected to the dose indicator;

The dispute over this part of claim 21 turns on the application of the "releasably connected" limitation to the Vystra. The parties do not dispute that the Vystra contains a setback component, which meets the sleeve limitation, a dose set knob, which meets the dose indicator limitation, and a lead screw, which meets the driving member limitation. Nor do they dispute that the sleeve is disposed between the dose indicator and the driving member. The sole point of disagreement is whether the setback is "releasably connected" to the dose set knob.

The parties also agree on certain key underlying facts. In the Vystra's "resting state" – that is, the state it would be in when the user has removed it from the packaging, but not yet started to set the dose or inject the insulin –, the setback and the dose set knob are disconnected.

It is only during injection, after the user presses the button, that the setback and the dose set knob are connected. Because that connection is released after injection (when the user releases the finger pressure on the button), the setback and dose set knob are connected only during injection. These facts are undisputed.

Sanofi's brief does not contain any persuasive argument to explain how, given these undisputed facts, the Vystra infringes the "releasably connected" limitation. Sanofi argues: "Defendants' interpretation fails because it is not the plain and ordinary meaning of 'connected,' and instead derives solely from improperly reading an extraneous limitation into the claim." (PPTB at 4.) Neither point succeeds. First, as to the ordinary meaning of connected, Sanofi contends: "The plain and ordinary meaning of 'connected' does not restrict when two components are connected." (Id.) That is a mix of true, false, and irrelevant. The ordinary meaning of "connected" may not set limits on when things *may* connect, but the ordinary meaning of "connected" is limited to those things that *are* connected. And that is the problem for Sanofi here. There is no evidence of record that the pen that will be sold and delivered to a purchaser at a pharmacy will contain within it a setback that is connected to a dose set knob. The evidence of record supports the finding that, in the product that Mylan will deliver to patients, the setback and the dose set knob will not be connected.[3]

There is no dispute here about the ordinary meaning of "connected." Neither side defined it, and there did not appear to be any confusion, uncertainty, or even discussion about

[3] Sanofi appears to confuse "connected" with "connectable." The evidence of record shows that the product that Mylan will deliver to patients contains a setback that is likely, at some future point, to become connected to the dose set knob, while the patient depresses the button to inject. The setback and dose set knob in the product as it is delivered to the patient at the pharmacy are properly described as "connectable," not "connected."

what the ordinary meaning of "connected" is. Sanofi's brief did not propose any definition of "connected," ordinary or otherwise. Using the ordinary meaning of "connected," the setback and the dose set knob in the Vystra are connected only during injection, and not at other times. The ordinary meaning of "connected" is not at issue.

The plain meaning of "releasably connected" requires that the objects are connected by default, and that the connection can be released. This construction of "releasably connected" is supported by the patent's specification, which describes an embodiment in which "the drive sleeve [is] releasably connected to the dose dial sleeve" and "clutch means are provided which upon depression of the button permit rotation between the dose dial sleeve and the drive sleeve." '844 patent, col.2 ll.1-4, 7-9. In the specification, then, "releasably connected" is used to describe an embodiment in which, in the resting state, the drive sleeve is connected to the dose dial sleeve, and that connection is released upon depression of the button, which permits relative rotation between the previously connected components. The evidence shows that the situation in the Vystra is the reverse of this.

This interpretation of "releasably connected" is not, as Sanofi contends, an attempt to import an extraneous claim limitation, but merely construes the claim according to its plain meaning and the intrinsic evidence. Sanofi contends that this is an improper attempt to incorporate embodiments into a claim, which is unexplained, unsupported, and thus purely rhetorical. Defendants are not implying a limitation of the device to its resting state.

To the contrary, Defendants are reading the claim as it is written, and applying it to the product they will sell. The claim says, "releasably connected," and there is no evidence that the pen that will be delivered to customers will contain the required releasable connection. No

embodiments and no limitations are being imported.

The Vystra product that will be delivered to customers at the pharmacy, in its packaging, will not infringe this limitation.

2. Infringement of claim 21: the piston rod holder

Claim 21 contains this language regarding the element of the piston rod holder:

> a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the distal end during dose dispensing;

In the PTB, Sanofi begins by stating, correctly, that, at trial, Mylan disputed only whether the Vystra piston rod holder was configured to prevent the piston rod from rotating during dose setting. Indeed, Mylan contends that the Vystra tower core is configured to prevent the piston rod from rotating during injection, not during dose setting. Sanofi argues that the Vystra tower core is configured to prevent the piston rod from rotating at all times.

The parties do not dispute the fundamental facts of the Vystra design: the tower core has a longitudinal slot that engages with a tab on the plunger rod and provides a keyed connection that has the capacity to prevent the plunger rod from rotating. Sanofi does not appear to dispute Mylan's contention that no drive mechanism applies rotational force to the plunger rod during dose setting. Instead, Sanofi contends that, absent this functionality in the tower core, the plunger rod might rotate due to other forces: "Without the Tower Core's keyed connection, the Plunger Rod would at times rotate during dose setting due to gravity and vibrational forces." (PPTB at 8.) This is speculation and has no basis in evidence. All that Sanofi offers in support is this testimony from Dr. Reinholtz:

> Q. And can you explain to us why the plunger rod could rotate if the keyed connection between the tower core and the plunger rod were not present?

> A. Sure. Once that keyed connection is removed, then the plunger rod is free to rotate off of the lead screw and any forces that act on it, including gravity or vibrations due to dialing the pen, for example, cause the plunger rod to rotate relative to the tower core.
>
> Q. Have you done an experiment to confirm that gravity or vibrations of the pen could cause the plunger rod to rotate during dose setting if this keyed connection of the tower core weren't present?
>
> A. Yes, I have.

(Tr. 111:1-14.) This is not evidence demonstrating the functioning of the tower core in the accused product; it is evidence about what happens when the pen is cut apart by an expert. Note the key qualification to Dr. Reinholtz' statement about gravity and vibration: "Once that keyed connection is removed." No one contends that the keyed connection gets removed during normal operation of the pen. This testimony, and the experiment that followed, say nothing about the normal operation of the pen. This Court is not persuaded that the operation of a dissassembled Vystra after an expert has cut it apart has any relevance to questions about its operation when intact. Sanofi has failed to point to any credible evidence that, were it not for the tower core's keyed connection, the plunger rod would rotate during dose setting due to the forces of gravity and vibration. There is simply no credible evidence that, during dose setting, the plunger rod is subject to any rotational force. If the plunger rod is not subject to any rotational force during dose setting, the tower core cannot be said to prevent its rotation in that phase of operation.

Mylan points to evidence that shows that, yes, certain components in the Vystra pen are designed to prevent the rotation of the plunger rod during dose setting, but by the functioning of the setback, not the tower core. As Mylan's expert, Mr. Quinn, who designed the Vystra pen,

explained:

> The other job of the tower core is to prevent the plunger rod from rotating during dose injection because it's during dose injection that the lead screw is turning, and that's when torque is applied to the plunger rod.

(Tr. 240:17-20.) Mylan also points to exhibit PTX-350, which Dr. Reinholtz identified as a "Becton Dickinson document describing the mechanical design of the pen." (Tr. 122:14-15.) Sanofi and Dr. Reinholtz relied on this document during the direct examination of Dr Reinholtz about the components of the Vystra and their functioning. On page 2 are diagrams of the pen, under the heading, "Device Operation: Dose Setting." (PTX-350 at PTX-0350.0002.) The text on page 2 reads:

> 1a. User dials DSK counter-clockwise, causing DSK to move out of the upper housing along a helical path
>
> 1b. Setback moves axially with the DSK, but without rotation due to a 1-way rachet engagement with the brake tower

(Id.) On page 4, under the heading, "Device Operation: Dose Administration," the text reads:

> 2a. User presses Button causing DSK and Setback to be coupled together (via clutch teeth) and rotate helically clockwise into the Body.
>
> 2b. Rotation of the Setback causes rotation of the Lead Screw due to keyed engagement between the leadscrew and setback.
>
> 2c. Rotation of the Lead screw causes axially [*sic*] displacement of the Plunger rod via internal threads on the Plunger rod.

(PTX-350 at PTX-0350.0004.) This is an exceptionally clear summary of the operation of the Vystra. On page 2, it makes clear that, during dose setting, the user rotates the dose set knob (DSK), but that rotation is not transferred to the drive train. Instead, the setback moves only axially, "without rotation," because of the one-way rachet engagement with the brake tower. (Id.) This states clearly that, during dose setting, the transmission of rotation from the DSK

beyond the setback, to the drive train, is prevented by the one-way rachet engagement of the setback.

The one-way ratchet engagement is an element of the setback, as shown in PTX-394. This document is an excerpt from the Vystra NDA, and was identified and relied on by Dr. Reinholtz during his direct examination. (Tr. 99:24-100:5.) A subsection within PTX-394 provides a narrative description of the design of the device, and counsel quoted from this subsection in the direct examination of Dr. Reinholtz. (Tr. 100:6-11, referencing PTX-394 at PTX-0394.0017.) On that same page of the Vystra NDA, it states:

> A one-way ratchet on the set back engages with splines (ridges) on the outside of the brake tower.
> . . .
> When the user dials up a dose, there is no pressure on the button to lock the DSK and set back together, so that the DSK can rotate freely whilst the set back remains rotationally static but moves axially with the DSK. The ratchets on the set back slide up the splines on the brake tower. . . To deliver the dose, the user pushes on the button. This locks the set back and DSK, so that they rotate and translate together. The rotation of the set back is transmitted to the lead screw, and the rotation of the lead screw drives the plunger rod forward to push the cartridge plunger stopper and deliver the dose.

(PTX-394 at PTX-0394.0017.) This confirms two key points: 1) the one-way ratchet is part of the setback; and 2) during dose setting, the dose set knob rotates freely while the setback remains rotationally static. It is not until the button is pressed that the dose set knob becomes locked to the setback, transmitting rotation to the lead screw. This evidence confirms that the part that prevents the transmission of rotational motion during dose setting is the setback.

Sanofi also argues that Mr. Quinn "confirmed that the Tower Core's keyed connection prevents the Plunger Rod from rotating, and that this keyed connection exists at all times, which would include dose setting." (PPTB at 8.) This statement is half true. There is no dispute

that, in an assembled and intact pen, the keyed connection between tower core and plunger rod exists at all times; there is no dispute that the piston rod holder, the tower core in the Vystra, holds the plunger rod at all times. This is not the issue. At issue is the claim language that specifies that the piston rod holder must be "configured to (i) prevent the piston rod from rotating during dose setting." The evidence shows that the one-way rachet on the setback is the component configured to prevent the piston rod from rotating during dose setting. The evidence does not support the assertion that the tower core is configured to prevent the piston rod from rotating during dose setting. The fact that the tower core/plunger rod keyed connection exists at all times is not sufficient to show infringement of the piston rod holder limitation in claim 21.

The evidence presented at trial supports the factual determination that, in the Vystra, it is the setback, not the tower core, that prevents the transmission of rotational movement during dose setting. The Vystra tower core does not prevent the piston rod from rotating during dose setting. Plaintiffs have not proven that the Vystra infringes the piston rod holder limitation in claim 21. The Vystra does not infringe the piston rod holder limitation in claim 21.

Mylan's PTB did not contest infringement of claim 22. Because claim 22 depends on claim 21, and this Court has determined that the Vystra does not infringe claim 21, claim 22 is not infringed.

3. Infringement of claim 25

Claim 25 depends on claim 24, which depends on claim 23, which depends on claim 21. Sanofi contends that the Vystra meets the limitations of these four claims. Mylan has already disputed claim 21 and additionally disputes that the Vystra meets the limitations stated in claims 23 and 25.

Claim 23 states: "The drug delivery device of claim 21 further comprising a clutch." Sanofi contends that the Vystra setback functions as both the sleeve of claim 21 and the clutch of claim 23. Mylan does not dispute that the setback can be understood to meet the sleeve limitation, and also to meet the clutch limitation, but contends that it is improper to have one physical component satisfy both limitations. Mylan argues: "Sanofi failed to identify a separate component as the claimed 'clutch' in claim 23."

Mylan argues that claim 23 states, " further comprising a clutch," and that the use of the word "further" requires a physically separate component. Mylan relies on two arguments. First, Mylan says that the inventors deliberately chose the word "further," and that choice must be honored. There is no dispute over that here: this Court will not disregard the word "further." The question is what it means.

Second, Mylan relies on the principle of claim differentiation to argue that "further" must require an additional and physically separate component.[4] After post-trial briefs were submitted, the parties filed a set of letters in which Sanofi argued that this claim differentiation argument was new and should be struck. This Court need not reach that dispute because the claim differentiation argument is unpersuasive, whether it is new or old. Mylan first states the principle of claim differentiation: a dependent claim must narrow the scope of the claim from which it depends. So far, so good. It is the next step in the argument that has the problem: "But Sanofi failed to identify a limitation in claim 23 that narrows claim 21 in any way."

[4] The appearance of the word "further" in a dependent claim is neither unusual nor surprising. The statute says: "a claim in dependent form shall contain a reference to a claim previously set forth and then specify a *further* limitation of the subject matter claimed." 35 U.S.C. § 112(d) (italics added.)

(DPTB at 9.) This makes no sense: the limitation in claim 23 that narrows claim 21 is the requirement of a clutch. The requirement of claim differentiation is satisfied because claim 21 does not require a clutch and claim 23 does. The scope of claim 23 is narrower than that of claim 21 because of the clutch limitation.

As to Mylan's argument that Sanofi has failed to identify a separate component as the clutch, if there is Federal Circuit authority for the proposition that one physical component cannot have different features that meet different claim limitations, Mylan has not cited it.

Mylan next argues that the part of the Vystra setback that does the clutching is different from the part of the setback that does the clicking, and that therefore the Vystra clutch does not provide audible clicks during dose cancelling, as required by claim 25. There is no dispute about the underlying facts. Sanofi cites a Becton Dickinson document that states: "Clicking during dose correction is caused by the double [ratchet] as it interacts with teeth inside the setback." (PTX-0350.0003.) Mr. Quinn testified that the teeth that do the clicking are different from the teeth that do the clutching. (Tr. 263:15-264:7.) Sanofi has not disputed this. The document just cited, PTX-350, shows that clicking during dose correction is caused by the interaction of teeth inside the setback with the double ratchet. That same document also states:

> 2a. User presses Button causing DSK and Setback to be coupled together (via clutch teeth) and rotate helically clockwise into the Body.

(PTX-0350.0004.) The Mylan NDA states:

> The set back is located inside the DSK. Axial teeth on the lower surface of the top flange of the set back engage with corresponding teeth in the DSK to lock the two together under axial loading.

(PTX-0394.0017.) This documentary evidence confirms Mr. Quinn's testimony: the clutch teeth are on the lower surface of the top flange of the setback, while the clicker teeth are on the

inside of the setback.

The dispute, then, is not about the facts, but whether these facts give rise to a finding of infringement. Sanofi argues that the setback is a clutch that provides audible clicks during dose canceling. Mylan argues that the clutching and clicking functions are provided by different parts of the setback. In opposition to Mylan's position, Sanofi says only: "This view is inconsistent with Court's construction for clutch, which defines the clutch as a component, not a set of features." (PPTB at 12.) In opposition to Sanofi's position, Mylan says only: "Sanofi did not establish why teeth unrelated to, and therefore having no role in, the clutching function should be considered part of the claimed 'clutch.'" (DPTB at 10.) Sanofi's argument is unpersuasive. During the Markman process, neither party raised the issue of whether the clutch was a component or a set of features, or whether it could be a part of a physically separate component.[5] The Court construed "clutch" as: "a component that can operate to reversibly lock two components in rotation." (Markman Opinion at 13.) Sanofi has offered no reason why "component" should imply "physically unique component that meets no other claim limitation" or "physically separate component" – particularly since this Court stated clearly in the Markman Opinion that it had not been presented with this issue.

Moreover, Mylan is correct: Sanofi has not established why teeth unrelated to clutching should be considered part of the clutch. Sanofi, as patentee, bears the burden of proof of infringement by a preponderance of the evidence, and this Court concludes that, as to claim 25, it

[5] Coincidentally, this Court made a note of this fact in the Markman Opinion, distinguishing the Lilly court's construction of "clutch" on the ground that the Lilly court had been presented with the issue of separateness of components, whereas the parties in the instant case had not raised that issue. (Markman Opinion at 11.)

has not met this burden. The Vystra clutch does not provide audible clicks during dose canceling. The Vystra does not contain a clutch that provides audible clicks during dose canceling, and does not infringe claim 25.

4. Infringement of claim 30

The parties agree that the question of whether Vystra infringes claim 30 turns on the question of whether the ordinary meaning of nut allows for external threads instead of internal threads: "The only contested issue is whether the Dose Stop is a nut because it has external threads." (PPTB at 13.) Sanofi points to the testimony of its expert, Dr. Reinholtz, who merely said: "some nuts have external threads." (Tr. 126:4.) The Court considers this testimony to be too vague to even be called conclusory. Neither party contends that, in the context of claim 30, "nut" has anything but its ordinary meaning to a POSA at the Priority Date. Dr. Reinholtz' testimony does not inform the Court about the ordinary meaning of "nut" to a POSA at the Priority Date. Sanofi also points to this exchange with Mr. Quinn:

> Q. Are things with external threads introduced as nuts, as far as you know?
> A. They are typically not.

(Tr. 247:23-25.) The Court does not find any admission about external threads in that exchange.

Mylan's post-trial brief is not more persuasive, also relying on vague comments by the experts. The Court finds that none of the experts had anything informative to say at trial about the ordinary meaning of "nut" to a POSA as of the Priority Date. Nor has either party pointed to any evidence in the intrinsic record that sheds light on this.[6] Given the absence of any intrinsic

[6] Mylan notes that the single embodiment in the '844 specification has an internally threaded nut. Absent some justification, this Court will not import a claim limitation from the sole embodiment.

evidence, or helpful expert testimony, this Court turns to general purpose dictionaries for guidance in ascertaining the ordinary meaning of "nut" to a POSA as of the Priority Date. In Comaper Corp. v. Antec, Inc., 596 F.3d 1343, 1348 (Fed. Cir. 2010), the Federal Circuit held:

> The patent specification does not assign or suggest a particular definition to the term "case." Therefore, in determining the ordinary and customary meaning of the claim term as viewed by a person of ordinary skill in the art, it is appropriate to consult a general dictionary definition of the word for guidance.

The same is true in the instant case: the patent specification does not assign or suggest a particular definition to the term "nut." It is therefore appropriate to consult a general dictionary definition of the word for guidance. Moreover, in Phillips, the Federal Circuit held:

> [W]e do not intend to preclude the appropriate use of dictionaries. Dictionaries or comparable sources are often useful to assist in understanding the commonly understood meaning of words and have been used both by our court and the Supreme Court in claim interpretation. A dictionary definition has the value of being an unbiased source "accessible to the public in advance of litigation." *Vitronics*, 90 F.3d at 1585. As we said in *Vitronics*, judges are free to consult dictionaries and technical treatises
>
> > at any time in order to better understand the underlying technology and may also rely on dictionary definitions when construing claim terms, so long as the dictionary definition does not contradict any definition found in or ascertained by a reading of the patent documents.
>
> *Id.* at 1584 n.6.

Phillips v. AWH Corp., 415 F.3d 1303, 1322-23 (Fed. Cir. 2005) (citations omitted). In the instant case, the parties have not pointed to any definition of "nut" to be found in the patent documents.

The Court consulted three online dictionaries to find the ordinary meaning of nut, as it relates to the mechanical component, and found these definitions:

1. "A small flat piece of metal or other material, typically square or hexagonal,

with a threaded hole through it for screwing on to a bolt as a fastener."[7]

2. "a perforated block usually of metal that has an internal screw thread and is used on a bolt or screw for tightening or holding something"[8]

3. "a block, usually of metal and generally square or hexagonal, perforated with a threaded hole so that it can be screwed down on a bolt to hold together objects through which the bolt passes."[9]

These online general dictionaries agree about the question of internal threads: a nut has a threaded hole, and thus an internal thread. The ordinary meaning of "nut" to a POSA, as of the Priority Date, is limited to an object with an internal thread. This is consistent with the embodiment disclosed in the specification, in which "[t]he nut 40 has an internal thread." '844 patent, col.4 ll.29-30.

The Vystra dose stop does not have an internal thread. The Vystra does not contain a nut within the meaning of claim 30. The Vystra does not infringe claim 30.

B. Invalidity

1. Invalidity pursuant to 35 U.S.C. § 112

Defendants contend that the '844 patent is invalid pursuant to 35 U.S.C. § 112 for lacking written description and failing to enable the full scope of the claims, on two grounds: 1) the '844 patent does not describe or enable embodiments having an internally threaded piston rod; and 2) to the extent the embodiment in the patent has a "piston rod holder," the patent does not describe or enable the configuration of that holder to prevent rotation during dose setting.

[7] https://www.lexico.com/en/definition/nut (last retrieved 2/25/2020.)
[8] https://www.merriam-webster.com/dictionary/nut (last retrieved 2/25/2020.)
[9] https://www.dictionary.com/browse/nut (last retrieved 2/25/2020.)

a. Written description

Mylan contends that certain elements within claim 21 are not described or enabled in the specification. Claim 21 recites "a piston rod comprising either an internal or an external fourth thread," as well as a "driving member comprising a third thread," where the third thread engages with the fourth thread of the piston rod. Mylan contends that the '844 patent does not describe either an internally threaded piston rod or an externally threaded driving member.[10] In support, Mylan cites the testimony of Mr. Leinsing, who stated that the '844 patent specification nowhere describes or shows an internally threaded piston rod. (Tr. 283:22-284:4; 285:19-22.) Mr. Leinsing also stated that there were no examples in the prior art of an injection pen with an internally threaded piston rod. (Tr. 286:3-5.) Mr. Leinsing also expressed the opinion that, based on the evidence in the '844 patent, he did not believe that the inventors had possession of an internally threaded piston rod. (Tr. 290:4-7.) He opined that it would have been very difficult, as of the Priority Date, for a POSA to design and implement an internally threaded piston rod (Tr. 285:23-286:1), and it would have required considerable experimentation (Tr. 290:18-22.)

Sanofi contends that, as to the elements of claim 21 in question, the written description and enablement requirements are met. At the outset, it is essential to note that Sanofi bears no burden of proof of the validity of the patent. The patent is presumed valid, and Mylan bears the burden of proof of invalidity by clear and convincing evidence. Sanofi-Aventis U.S., LLC v. Dr. Reddy's Labs., Inc., 933 F.3d 1367, 1375 (Fed. Cir. 2019) ("A patent is presumed valid, and

[10] There is no dispute that the specification adequately describes and enables an externally threaded piston rod.

overcoming that presumption at the district court requires clear and convincing evidence.")

Nonetheless, the Federal Circuit has given this guidance:

> The party challenging the validity of a patent always has the burden of persuading the trial court of invalidity. However, once a challenger has presented a prima facie case of invalidity, the patentee has the burden of going forward with rebuttal evidence. But, all that means is that even though a patentee never must submit evidence to support a conclusion by a judge or jury that a patent remains valid, once a challenger introduces evidence that might lead to a conclusion of invalidity—what we call a prima facie case—the patentee would be well advised to introduce evidence sufficient to rebut that of the challenger.

Prometheus Labs., Inc. v. Roxane Labs., Inc., 805 F.3d 1092, 1101-02 (Fed. Cir. 2015) (citations omitted.) In the instant case, Mylan has introduced evidence that might lead to a conclusion of invalidity, and the Court now considers Sanofi's rebuttal evidence.

The rebuttal case in Sanofi's brief tracks Dr. Slocum's testimony:

> A POSA knows that there are only two variations regarding the threading between a piston rod and a driver: internal/external and external/internal. Thus, when the '844 Patent broadly discloses a pen injector having a piston rod with a threaded portion connected to a threaded drive sleeve, a POSA would understand that the piston rod's threaded portion could be internal or external.

(PPTB at 34.) Sanofi then points to Dr. Slocum's testimony that leadscrew mechanical devices were centuries old and, next, to the fact that Dr. Slocum cited two patents for medical devices (although these devices were motor-driven pumps, not injector pens.) Dr. Slocum testified that he had written a 1995 textbook with a section about leadscrew devices. (Tr. 497:8-498:7.) Sanofi then makes a number of challenges to Mylan's invalidity case.

Even before considering Dr. Slocum's testimony, the Court notes that Sanofi's rebuttal argument is quite limited: Sanofi contends, in short, that leadscrew devices were well-known in the art, that a POSA reading the patent's opening summary of the device would already be envisioning the two simple options (internally and externally threaded piston rod) that are

available for connecting the piston rod to the drive sleeve, and two prior art medical device patents disclose an internally threaded piston rod driven by an externally threaded driver.

Before examining the evidence, the Court considers these arguments in light of the relevant legal standard. The Federal Circuit has set forth these fundamental principles for the inquiry into whether a patent is invalid for failure to meet the written description requirement:

> Since its inception, this court has consistently held that § 112, first paragraph, contains a written description requirement separate from enablement, and we have articulated a fairly uniform standard, which we now affirm. Specifically, the description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed. In other words, the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date.
>
> The term "possession," however, has never been very enlightening. It implies that as long as one can produce records documenting a written description of a claimed invention, one can show possession. But the hallmark of written description is disclosure. Thus, "possession as shown in the disclosure" is a more complete formulation. Yet whatever the specific articulation, the test requires an objective inquiry into the four corners of the specification from the perspective of a person of ordinary skill in the art. Based on that inquiry, the specification must describe an invention understandable to that skilled artisan and show that the inventor actually invented the invention claimed.

Ariad Pharm., Inc. v. Eli Lilly & Co., 598 F.3d 1336, 1351 (Fed. Cir. 2010) (citations omitted.) The last sentence is key here, because it sets forth a two-pronged test: the specification must both describe an invention understandable to the POSA, **and** the specification must show that the inventor actually invented the invention claimed.

Sanofi's arguments are directed to the first prong, but not the second. Sanofi contends no more here than that the specification describes an invention easily understandable to the POSA. Sanofi has made no argument that the specification shows that the inventor actually invented the invention claimed. Sanofi's brief does not address this part of the standard. Of

course, it has no obligation to do so.

With that in mind, the Court considers Sanofi's evidence in support, which is principally the testimony of Dr. Slocum. Dr. Slocum was persuasive on two points: 1) lead screw systems were well-known in the prior art; and 2) medical devices with internally threaded piston rods were known in the prior art. These points were persuasive because Dr. Slocum's testimony was backed up with documentary evidence: his textbook and the prior art patents. As to the points which were not backed up with supporting evidence, the Court found Dr. Slocum's testimony to be glib, unpersuasive, and worthy of little weight. As already discussed, Dr. Slocum testified that, in essence, a POSA reading the patent's opening summary of the device would already be envisioning the two simple options (internally and externally threaded piston rod) that are available for connecting the piston rod to the drive sleeve. As to these points, Sanofi offers only Dr. Slocum's testimony, without any supporting evidence. Mylan has argued that there are no examples of prior art injection pens with an internally threaded piston rod and, while Sanofi has no obligation to disprove this, it offered no evidence that rebutted it.

Dr. Slocum's testimony on these points appeared simplistic. For example, both in the brief and while examining Dr. Slocum, Sanofi cited to the '844 specification, column 1 line 47 to column 2 line 9, which is, indeed, a general statement about the device and many of its components. At trial, Dr. Slocum was asked about this section of the specification, and he went through it, line by line. When he got to the part about the piston rod threads, he said, first reading the line aloud:

> 'Preferably the piston rod has a first threaded portion at first end and a second threaded portion at a second end.' It just says "threaded." There's only two things it can be. So in the POSA's mind it's -- in your brain you see external/internal.

(Tr. 494:22-495:1.) Here, Dr. Slocum glosses over the word that starts the sentence: "preferably." That might not otherwise mean too much, except that Dr. Slocum relies on this sentence as the basis for his assertion that "there's only two things it can be," and he has disregarded the key word alerting the reader to the fact that the scope of the invention is broader than the remainder of the sentence indicates. This is a tip-off that Dr Slocum may be oversimplifying. Moreover, even if there are just two options for each thread, shouldn't that make four options for a rod with two threaded ends, not two?

What followed at trial was an examination of Dr. Slocum about a diagram he had drawn at his deposition, in which he sketched an internally threaded piston rod with a driver that he called a "stinger." He stated:

> Q. Now, what knowledge did you use to make this drawing?
>
> A. Well, it's just all the material in the patent and then what the POSA also has in their head, what I put in the spreadsheet. That's it.
>
> Q. Is it your opinion that a POSA reading the '844 specification and having the knowledge in the art about leadscrew drive systems, for example, would be able to envision arrangements where the piston rod has an internal thread that is engaged with a driver having an external thread?
>
> A. Yes. They would just do what I did here.

(Tr. 504:1-11.) The implication here is that this business of changing the externally threaded piston rod – and there is no dispute that an externally threaded piston rod is adequately described in the specification – to an internally threaded one, connecting to an externally threaded drive sleeve, is simple and basic for the POSA, just using the information in the patent and ordinary background knowledge that a POSA would have. Neither Dr. Slocum nor Sanofi have provided other evidence which supports this.

Rather, perhaps inadvertently, Dr. Slocum provided evidence that this was much oversimplified. On cross-examination, Dr. Slocum was questioned about the deposition diagram and an Excel spreadsheet he had made in regard to the question of whether the stinger would buckle when used. Dr. Slocum appeared to agree that he could use the spreadsheet to determine whether the stinger would buckle. (Tr. 580:6-9.) Dr. Slocum, on the stand, began altering values in the spreadsheet to answer this question, narrating as he went.[11] He mentioned the following design choices: 1) the root diameter of the piston rod thread (Tr. 580:13-24); 2) stinger length (582:1-3); 3) choice of plastic (Vectra) and its modulus elasticity (Tr. 582:5-25); 4) choice of different plastic (Delrin) for another part (Tr. 583:8-10); and 5) a question of whether to weld the two parts or have a snap fit (583:4-13). At this point, the attorneys started worrying about time, and Dr. Slocum gave this rapid monologue as he worked on the spreadsheet:

> So go down. Hold on. Do you see where it says 1.1 shaft with flats and then shaft without flats. I need the 1.6. Click on that. Do you see thin max over thin TB? And now go to the buckle. Then click on the buckle where it says "no." Hold on. So what happens here is it's taking the with and without, and the buckling formula depends upon the modulus. It's linear with the modulus. It's going to be linear in that other length but also will depend upon the end conditions.
>
> In the stinger you will have what is called -- it will be fixed on one end and simply supported on the other. And the leadscrew that's in these pen injectors, it's a simple-simple connection. There's a coefficient, it's called C, when you do the buckling equation. The difference between the simple-simple and fixed simple is how you support it. It's about almost a factor 3. So the leadscrew buckling calculation that was done here was for the piston rod which you could model as simple-simple. It's just two simple supports. If you want to do the buckling calculation for the stinger, it's clamped simple. It's about three times higher. But even if we keep the same simple-simple, you see it's not going to buckle.

[11] Sanofi, in its brief, called this "a live simulation at trial." (PPTB at 37.)

(Tr. 584:4-585:2.) Dr. Slocum's live simulation testimony is credible evidence that the design choices needed to answer only the single question of whether the stinger would buckle were numerous and complicated. It seems safe to infer that the design choices that would be required to produce a fully functional injection pen, with an internally threaded piston rod, would be more numerous and more complicated, than what Dr. Slocum demonstrated in this simulation.

This inference is supported by the deposition testimony of Robert Perkins, one of the named inventors on the '844 patent, who stated:

> Q. And how about if you took the threads that are on the outside of the button end of the piston rod 20, put those on the inside instead of the outside and reassemble the pen, would that work?
>
> A. Again, you can't look at one feature on its own. It's part of a complex system. So a cause and effect. If you change one thing, you have to look at the bigger picture and make other amendments to correct for that change.
>
> Q. So if you put the threads of the piston rod on the inside of the piston rod, you would then have to go and make modifications to other components in the pen before you would have a functional design again?
>
> A. A theoretically functional design, yeah.
>
> Q. Why did you say theoretically?
>
> A. Because there is other constraints that need to be considered as well.

(DTX-2921 at 114:17-115:12.) The most important point here is that an inventor of the '844 pen characterized it as a complex system to modify: you cannot look at one feature on its own, but must consider modifying multiple parts of that complex system. Although Mr. Perkins did not assess the degree of complexity, his testimony supports Mylan's position that this would be complicated, and is evidence against Sanofi's contention that it would be a matter of a simple choice between two well-understood options.

Turning back to the bigger picture, Sanofi contends that it would have been a fairly simple matter for a POSA to use background knowledge with the teachings of the '844 patent to make and use an injection pen with an internally threaded piston rod. Mylan contends that it would have been very complicated. The evidence at trial is: 1) Dr. Slocum suggests that it is so simple that an MIT professor can draw it in a few minutes; and 2) Dr. Slocum demonstrates that the design choices for the stinger alone are extremely complicated. The Court finds Dr. Slocum's spreadsheet demonstration to be credible and his testimony to the contrary to be undermined by the spreadsheet demonstration. As stated, the Court concludes that Dr. Slocum's testimony about the simplicity of modifying the embodiment disclosed in the '844 patent to work as an injection pen with an internally threaded piston rod is not credible and not deserving of any weight. Nor does this Court find that Dr. Slocum's deposition diagram deserves any weight as evidence of the simplicity of making a modified design: it is similarly undermined by the spreadsheet demonstration. The Court further determines, as a factual matter, that a POSA who wanted to modify the embodiment disclosed in the '844 patent to work as an injection pen with an internally threaded piston rod would face a complicated design task with many choices. The evidence presented at trial does not support Sanofi's contention that a POSA could easily modify the design of the injection pen disclosed in the '844 patent specification to create a functional pen with an internally threaded piston rod.

With this foundation, the Court returns to the two-pronged Ariad test: does the specification describe an invention understandable to the POSA, and does the specification show that the inventor actually invented the invention claimed? There is no dispute that the specification does not disclose an internally threaded piston rod. Sanofi argues that Federal

Circuit law does not require the inventor to "spell out every detail." This is true, but let us consider what the Federal Circuit has said about that:

> A claim will not be invalidated on section 112 grounds simply because the embodiments of the specification do not contain examples explicitly covering the full scope of the claim language. That is because the patent specification is written for a person of skill in the art, and such a person comes to the patent with the knowledge of what has come before. Placed in that context, it is unnecessary to spell out every detail of the invention in the specification; only enough must be included to convince a person of skill in the art that the inventor possessed the invention and to enable such a person to make and use the invention without undue experimentation.

LizardTech, Inc. v. Earth Res. Mapping, Inc., 424 F.3d 1336, 1345 (Fed. Cir. 2005) (citations omitted). As LizardTech explains, while it is unnecessary to spell out every detail of the invention in the specification, there must be enough included to convince a POSA that the inventor possessed the invention. Although Sanofi's brief acknowledges that this is the standard, its sole argument that the standard has been met is: "Dr. Slocum testified that the broad embodiment described at column 1, line 47 to column 2, line 9 of the '844 Patent conveyed to a POSA possession of an internally threaded piston rod." (PPTB at 36.) The citation to the transcript that follows this assertion references Mr. Leinsing's testimony, not Dr. Slocum's.

Sanofi's assertion about Dr. Slocum's testimony is not supported by the evidence. During the examination of Dr. Slocum about the contents of columns 1 and 2 of the specification, Dr. Slocum did not testify that the specification conveyed to a POSA that the inventors had possession of an injection pen with an internally threaded piston rod, nor anything close to that. For one thing, Dr. Slocum was not an expert in the design of injection pens, and he admitted that, as of the Priority Date, he had no personal experience with injector pens. (Tr. 521:8-10.) Dr. Slocum was not admitted as an expert in the design of injection pens. The

bottom line is that Sanofi has pointed to no evidence that the specification conveyed to a POSA that the inventors had possession of an injection pen with an internally threaded piston rod. To the extent that Dr. Slocum's testimony about the simplicity of envisioning such a design could be viewed as supporting an inference that the inventors had such possession, this Court has rejected that testimony as not credible and as contradicted by Dr. Slocum's spreadsheet demonstration, which showed persuasively the complexity of modifying the design depicted in the '844 specification.

Mylan offered the testimony of its design expert, Mr. Leinsing, who stated that the specification does not offer evidence that the inventors had possession of an injector pen with an internally threaded piston rod. With this Court's rejection of Dr. Slocum's testimony about the ease with which a POSA would envision such a design, Mylan's evidence is unrebutted. As already stated, in Ariad, the Federal Circuit set forth this standard for the written description requirement of § 112: "the test for sufficiency is whether the disclosure of the application relied upon reasonably conveys to those skilled in the art that the inventor had possession of the claimed subject matter as of the filing date." Ariad, 598 F.3d at 1351. The Court concludes that Mylan has proven, by clear and convincing evidence, that the disclosure of the '844 patent does not reasonably convey to a POSA that the inventor had possession of all of the subject matter of claim 21 as of the Priority Date. Claim 21 of the '844 patent is invalid for failure to meet the written description requirement.

Mylan also contends that claim 21 fails to meet the written description requirement with regard to these limitations: "a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting." In opposition, Sanofi

points to Dr. Slocum's detailed testimony that, in the embodiment disclosed in the '844 specification, insert 16 meets those limitations. (Tr. 512:2-513:9.) Later in Mylan's PTB, Mylan concedes that the specification *does* teach one way to make and use a piston rod holder to prevent rotation, using oppositely disposed threads. (See FOF ¶¶ 207-208.) This concession undermines Mylan's argument that the specification fails to convey that the inventors possessed an injection pen with the specified piston rod holder. The Court finds that Dr. Slocum's testimony is supported by Mylan's concession and credits both. Mylan has failed to show, by clear and convincing evidence, that claim 21 is invalid for lack of written description of the "piston rod holder."

b. Enablement

Mylan also argues that claim 21 is invalid for lack of enablement, pursuant to § 112. "To be enabling, the specification of a patent must teach those skilled in the art how to make and use the full scope of the claimed invention without undue experimentation." Trs. of Bos. Univ. v. Everlight Elecs. Co., 896 F.3d 1357, 1362 (Fed. Cir. 2018). As to claim 21, Mylan's post-trial brief makes its § 112 enablement argument in a single paragraph, in which it points to two pieces of evidence: 1) Mr. Perkins' testimony that redesigning the '844 embodiment to have internal threading would require making additional changes to other components to have "a theoretically functional design" because "it's part of a complex system;" and 2) Mr. Leinsing's testimony that such a redesign would have been difficult and required many changes. While this evidence supports Mylan's position, Mylan has not come close to proving invalidity by clear and convincing evidence. Sanofi argues that the opinions from Mr. Leinsing that Mylan relies on are conclusory, or supported by irrelevant considerations such as

manufacturing.

There is no dispute that the ’844 patent nowhere teaches how to make and use an injector pen with an internally threaded piston rod. Mr. Leinsing testified:

> Q. Now, in the specification did you find anything that taught about making those threads on the piston rod internal?
>
> A. There's nothing in the specification or the figures that mentions anything about internal threads on the piston rod.
>
> Q. So given this, how difficult would it have been at the time for a POSA to design and implement an internally threaded piston rod?
>
> A. It would have been very difficult. There -- would have required a lot of changes. And keeping in mind both myself and Sanofi, experts on both sides, there's not a single piece of prior art of a pen injector with threads on the inside of a piston rod. It just doesn't exist. So it's not something that's inherent that a person of skill in the art would have understood in 2003, so it's not -- not only is it not inherently known, it was not taught in the patent in any way.
>
> Q. Now, Dr. Slocum at one of his depositions said essentially a person of ordinary skill in the art would be able to come up with an internally threaded piston rod and sketched out a document. Did you see that?
>
> A. Yes, I did.
>
> Q. Did you consider that in connection with your opinions in this case?
>
> A. Yes, I did.
>
> MR. CARSTEN: Let's take a look at DTX-2846 if we might.
> BY MR. CARSTEN:
> Q. What is that, Mr. Leinsing?
>
> A. This is the sketch that Dr. Slocum made during one of his depositions.
>
> Q. Do you agree that a person of ordinary skill in the art would be able to call to mind this structure based upon the disclosures of the '844 patent in the background of a person of skill in the art that the person brings with her?
>
> A. No. As you can see, even in his sketch that he's trying to create, there's a lot of detail that's required. It creates a lot of structural problems. It creates a lot of

manufacturing problems.

(Tr. 285:19-287:5.) This testimony is followed by several pages of examination and testimony on the issues of possible buckling of the piston rod and whether to weld certain parts together. (Tr. 287-290.)

Mr. Leinsing's testimony supports Mylan's contention that the POSA would have had difficulty with making and using an injection pen with an internally threaded piston rod. The problem for Mylan, though, is that it has not focused on the requirements of Federal Circuit law. Mr. Leinsing's testimony supports Mylan's contention that the POSA would have had difficulty with making and using an injection pen with an internally threaded piston rod. The problem for Mylan, though, is that it has overlooked a key element of the Federal Circuit enablement standard: the specification must teach a POSA how to make and use an invention *without undue experimentation*. Mylan's post-trial brief does not even address this element, much less persuade the Court that the evidence clearly and convincingly shows that a POSA would be unable to make and use the claimed invention without undue experimentation.

The Federal Circuit's decision in Cephalon, Inc. v. Watson Pharm., Inc., 707 F.3d 1330, 1338 (Fed. Cir. 2013), is instructive. The district court had found the claim at issue invalid for want of enablement, and Watson, the challenger, had relied heavily on expert testimony that practice of the invention, based on the patent disclosure, would be "difficult" and "complicated." Id. The Federal Circuit found that the expert's conclusions in this regard were "largely unsupported" and should therefore carry little weight. Id. The district court also weighed in Watson's favor testimony from the opposing expert that some routine experimentation would be required. Id.

The Federal Circuit held that the district court had erred, particularly in its understanding of the experimentation requirement. Id. The Federal Circuit explained:

> The question of undue experimentation is a matter of degree, and what is required is that the amount of experimentation not be unduly extensive. For example, the fact that a clinician's involvement may be necessary to determine effective amounts of the single compound effervescent agent and its corresponding soluble acid source does not itself constitute undue experimentation. In addition, extensive experimentation does not necessarily render the experiments unduly extensive where the experiments involve repetition of known or commonly used techniques. Thus, the focus is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance.
>
> Permissible experimentation is, nevertheless, not without bounds.

Id. at 1338-39 (citations omitted). The Federal Circuit stated: "Watson had the burden to show by way of testimony or documentary evidence the amount of experimentation needed to" make and use the claimed invention. Id. at 1339. It found that Watson had not shown that the experimentation needed would have been excessive, such as by taking "an unreasonable length of time." Id. The Federal Circuit concluded:

> Unsubstantiated statements indicating that experimentation would be "difficult" and "complicated" are not sufficient. In light of the lack of evidence on the record of undue experimentation, the district court erred as a matter of law in holding that Watson proved its case on enablement by clear and convincing evidence.

Id.

In the instant case, similarly, Mylan has not shown that the experimentation needed would be excessive. Rather, like Watson, it has pointed to unsubstantiated expert testimony that the experimentation would be difficult and complicated. As Cephalon makes clear, this is insufficient to prove invalidity for want of enablement by clear and convincing evidence. Mylan did not develop evidence showing the quantum of experimentation that would be needed

to make and use the invention at issue. From the evidence presented at trial, Mylan showed that a substantial amount of experimentation would be needed. This, however, is not sufficient under the law. In 1982, the predecessor court to the Federal Circuit stated:

> The test is not merely quantitative, since a considerable amount of experimentation is permissible, if it is merely routine, or if the specification in question provides a reasonable amount of guidance with respect to the direction in which the experimentation should proceed to enable the determination of how to practice a desired embodiment of the invention claimed.

Ex parte Mariana Jackson et al., 217 U.S.P.Q. (BNA) 804, 806 (Bd. Pat. App. & Interferences November 12, 1982). This continues to be the law. Mylan made no showing of whether the experimentation required would or would not be routine. As to the internally threaded piston rod, Mylan has failed to prove, by clear and convincing evidence, that claim 21 is invalid for want of enablement.

Mylan also contends that claim 21 is invalid for want of enablement of the "piston rod holder" limitation. Mylan's position has two principal defects. First, Mylan's PTB concedes that the specification does teach one way to make and use a piston rod holder to prevent rotation, using oppositely disposed threads. (See FOF ¶¶ 207-208.) Second, despite this concession, the PTB then makes the conclusory assertion that "the POSA could not make and use the full scope of the claims without undue experimentation;" no evidence in support is cited. (DPTB at 17.) As to the piston rod holder limitation, Mylan has failed to prove, by clear and convincing evidence, that claim 21 is invalid for want of enablement.

There is no contradiction in finding claim 21 invalid for failure to meet the written description requirement, but also finding that Mylan has failed to show claim 21 invalid for lack of enablement. Although both the written description and enablement requirements derive from

paragraph 1 of 35 U.S.C. § 112, the substance of the requirements and the applicable legal standards differ significantly. As the Federal Circuit has explained, "the fact that an invention may be enabled does not mean it is adequately described, and vice versa." Nuvo Pharm. (Ir.) Designated Activity Co. v. Dr. Reddy's Labs. Inc., 923 F.3d 1368, 1382 (Fed. Cir. 2019). The Federal Circuit carefully analyzed the relationship between the two requirements in Ariad, in which it stated:

> Perhaps there is little difference in some fields between describing an invention and enabling one to make and use it, but that is not always true of certain inventions, including chemical and chemical-like inventions. Thus, although written description and enablement often rise and fall together, requiring a written description of the invention plays a vital role in curtailing claims that do not require undue experimentation to make and use, and thus satisfy enablement, but that have not been invented, and thus cannot be described.

598 F.3d at 1352. As to claim 21 in the instant case, written description and enablement did not rise and fall together at trial. Although it is clear that the ´844 specification neither discloses an injection pen with an internally threaded piston rod, nor shows how to make and use one, the reason for the difference in this Court's validity determinations may be as simple as this: Mylan assembled a much more convincing case on the written description problem than it did on enablement. Even though the disclosure in the specification never changed, while Mylan convincingly demonstrated that the specification failed to reasonably convey that the inventor had possession of the claimed subject matter, it neglected to develop evidence about the experimentation that would be needed to make and use it, and therefore failed to convincingly demonstrate lack of enablement.

2. Invalidity pursuant to 35 U.S.C. § 103

Mylan contends that the claims at issue are invalid as obvious, pursuant to 35 U.S.C. §

103. During closing arguments, Sanofi cited the stipulation entered into by the parties dated June 14, 2019, which was Ordered and filed by the Court on June 17, 2019 (hereinafter, the "IPR Stipulation.") In the IPR Stipulation, the parties agreed that, in this case, Defendants would not pursue the grounds upon which certain IPRs had been instituted by the PTAB, in reference to a number of patents, including the patent at issue in this trial, the '844 patent. As to the '844 patent, the IPR Stipulation described those grounds as follows:

- Obviousness over Giambattista '794 in combination with Steenfeldt-Jensen '004 (claims 24-29)
- Obviousness over Giambattista '794 in combination with U.S. Patent No. 6,582,404 ("Klitgaard '404") (claim 30)
- Obviousness over Steenfeldt-Jensen '004 alone (claims 21-29)
- Obviousness over Steenfeldt-Jensen in combination with Klitgaard '404 (claim 30)

(IPR Stipulation at 2.) During its closing argument, Mylan responded:

> Now, there's been suggestion that we're creating a brand-new argument. That's absolutely not true. We stand by every word in that stipulation from back in June, Your Honor. We relied heavily upon Chanoch in order to demonstrate that the change of the threads, the swap of the threads in the slot, would be reasonably expected to succeed by a person of ordinary skill in the art. That's our argument. That's what we stick to.

(Tr. 650:20-651:2.) Despite having stipulated that it would not assert an obviousness argument over SJP alone (claims 21-29), and despite using the subheading, "Steenfeldt-Jensen In View Of Chanoch Render The Asserted Claims Obvious (DPTB at 18), Mylan's post-trial brief makes many assertions about SJP alone. This Court honors and enforces the IPR Stipulation, and this Court will not consider, for claims 21 through 29, obviousness arguments based on SJP alone, which have been waived.

As to obviousness over SJP in view of Chanoch, Mylan makes a somewhat complicated

argument which can be summarized simply: Mylan argues that all of the elements of claim 21 can be found somewhere in SJP, but definitely in the combination of SJP and Chanoch. And, with that, Mylan goes no further. This is a fragment of an obviousness argument. As already stated, this Court will not consider the argument that claim 21 is invalid for obviousness based on SJP alone, pursuant to the IPR Stipulation. Mylan is left with an argument of obviousness based on SJP in view of Chanoch, in line with the subheading. Even if, for the sake of discussion, this Court agreed that every element of claim 21 is found somewhere in those two references – and the Court need not reach that question – , where is the rest of the theory?

The Federal Circuit has summarized the fundamental principles of the law of obviousness as follows:

> Under § 103, a patent may not issue "if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains." 35 U.S.C. § 103 (2006). Obviousness is a question of law based on underlying factual determinations, including: (1) the scope and content of prior art; (2) differences between prior art and claims; (3) the level of ordinary skill in the art; and (4) objective indicia of nonobviousness. *Graham v. John Deere Co.*, 383 U.S. 1, 17-18, 86 S. Ct. 684, 15 L. Ed. 2d 545 (1966). A party asserting that a patent is obvious must demonstrate by clear and convincing evidence that a skilled artisan would have had reason to combine the teaching of the prior art references to achieve the claimed invention, and that the skilled artisan would have had a reasonable expectation of success from doing so.

Par Pharm., Inc. v. TWi Pharm., Inc., 773 F.3d 1186, 1193 (Fed. Cir. 2014). The final sentence from this quote states a standard that Mylan has not come close to meeting. Mylan does not even attempt to show that the POSA would have had a reason to combine the teachings of SJP and Chanoch to achieve the invention of claim 21, or that the POSA would have had a reasonable expectation of success from doing so. Mylan's first obviousness argument fails.

Mylan's next subheading reads: "Claim 22: Steenfeldt-Jensen And Chanoch Render Obvious A Piston Rod That Has 'A Circular Cross-Section.'" (DPTB at 23.) The Court makes the exact same analysis here: even if, for the sake of discussion, this Court agreed that every element of claim 22 is found somewhere in those two references – and the Court need not reach that question – , where is the rest of the theory? Where are the arguments about motivation to combine and reasonable expectation of success? Mylan's second obviousness argument fails.

The next subheading states: "Claim 30: A 'Nut That Tracks Each Set Dose of Medicament' Is Obvious Over Steenfeldt-Jensen And The Prior Art." (DPTB at 25.) In this single paragraph, Mylan argues that a dose tracking nut was known and used by others in the art, pointing to FlexPen and Klitgaard. In the IPR stipulation, Mylan waived the argument that claim 30 is obvious over SJP and Klitgaard, and this Court will not consider it. This leaves the combination of SJP and FlexPen.[12]

It is at this point that Mylan addresses the motivation to combine for the first time, contending: "Sanofi did not dispute that the POSA would be motivated to add and could and would add a dose tracking nut." (DFOF ¶ 121.) Mylan cites two sections of testimony. In the first, Mr. Leinsing testified that: 1) as of the Priority Date, an ISO standard required injector pens to have dose tracking (Tr. 317:1-18); 2) FlexPen has a dose tracking nut (Tr. 318:10-21); and 3) a POSA would have known how to use a nut for dose tracking (Tr. 319:13-22). The second

[12] Sanofi contends that Mylan failed to prove by clear and convincing evidence that FlexPen was available in the United States before the Priority Date. As Mylan observes, Sanofi is in a tricky position with this one: having made Dr. Slocum's analysis of the FlexPen a key point in its invalidity rebuttal case, Sanofi cannot have it both ways. If FlexPen is not prior art, Sanofi's expert's analysis of it is irrelevant. That may be why Sanofi does not object too strenuously to FlexPen as prior art. In any case, Sanofi asserts that, even if the Court found that FlexPen is valid prior art, all of Mylan's obviousness arguments would still fail.

section that Mylan cites is the first 48 pages of Dr. Slocum's testimony. The Court will not guess what Mylan was hoping the Court would find there, but the Court will comment that it did not find any testimony about a dose tracking nut.

Having looked at the underlying evidence, the Court considers Mylan's assertion: "Sanofi did not dispute that the POSA would be motivated to add and could and would add a dose tracking nut." (DFOF ¶ 121.) This assertion goes far beyond the cited evidence. The cited testimony from Mr. Leinsing supports only these relevant inferences: 1) a POSA would have been motivated to make a pen injector with dose tracking because of the requirement of the ISO standard; and 2) the FlexPen used a dose tracking nut to track dosing. There is a sizable gap between these inferences and clear and convincing evidence that claim 30 is obvious in view of SJP and FlexPen. For starters, Mr. Leinsing did not testify that a POSA would have found it obvious to combine SJP and FlexPen to create the device of claim 30, nor that the POSA would have had a reasonable expectation of success in doing so. At trial, Mylan does not appear to have asked its expert for an opinion on those questions, and he did not give any. Mylan's third obviousness argument fails.

Mylan next argues that FlexPen renders obvious all the claims, but offers very little in support. This assertion is both cryptic and incomplete.

Lastly, Mylan argues that GiaP renders both claims 21 and 22 obvious. As to claim 21, Mylan first points to the fact that Sanofi stipulated that GiaP contained every limitation in claim 21 except for one: "a piston rod holder that is rotatably fixed relative to the housing and configured to (i) prevent the piston rod from rotating during dose setting and (ii) permit the piston rod to traverse axially towards the distal end during dose dispensing." Mylan contends

that GiaP does in fact meet this limitation, notwithstanding the undisputed fact that the device does not meet this claim limitation during one phase of operation, cartridge replacement. The argument that the GiaP device meets this limitation during two out of three phases of operation is not persuasive. As to claim 22, because claim 22 depends on claim 21, having failed to persuade that claim 21 is obvious over GiaP, Mylan cannot succeed with claim 22.

In light of this Court's conclusion that Mylan has failed to demonstrate any motivation to combine the teachings of the prior art references, and failed to meet its burden of proof of invalidity based on obviousness by clear and convincing evidence, there is no need for a detailed discussion of secondary considerations of non-obviousness to uphold the patent. But see Geo M. Martin Co. v. All. Mach. Sys. Int'l LLC, 618 F.3d 1294, 1304 (Fed. Cir. 2010) ("Secondary considerations of non-obviousness must be considered when present.") The Court notes, however, that Mylan has made a substantial showing that the nexus between the commercial success and the '844 patent is tenuous at best, given the overwhelming success of the medicine injected, insulin glargine. Furthermore, the Orange Book currently states that the Lantus® SoloSTAR® pen is protected by eighteen patents, and Sanofi's evidence did not support any conclusion about which of these eighteen, if any, might account for any success. Mylan has also made a substantial demonstration that industry praise, under the circumstances of this case, is of minimal importance, given the fact that it primarily consisted of industry awards for which Sanofi nominated itself, or for which there were numerous award recipients in the same category.

The Court concludes that Sanofi has failed to prove that the Vystra infringes claims 21, 22, 25, or 30. Mylan has proven, by clear and convincing evidence, that claim 21 is invalid for failure to meet the written description requirement in 35 U.S.C. § 112 ¶ 1, and therefore Mylan

has proven that claims 22, 25, and 30, which depend on claim 21, are invalid as well. Mylan has failed to prove, by clear and convincing evidence, that claims 21, 22, 25, and 30 are invalid under their theories based on § 103 obviousness or the enablement requirement in 35 U.S.C. § 112 ¶ 1. This Court determines that claims 21, 22, 25, and 30 are not infringed by the Vystra. This Court determines that claims 21, 22, 25, and 30 are invalid for lack of adequate written description. Judgment will be entered in favor of Mylan on Sanofi's infringement claims and on Mylan's affirmative defense of invalidity for failure to meet the written description requirement in 35 U.S.C. § 112 ¶ 1.

Pursuant to FED. R. CIV. P. 52(a), the Court presents its findings of fact and conclusions of law.

FINDINGS OF FACT

I. This Opinion incorporates by reference all stipulated facts set forth in the Final Pretrial Order.

II. Based on the evidence presented at trial, this Court now makes the following findings of fact:

1. The '844 patent descends from application No. 10/790,225, and claims priority to foreign application GB 0304822.0, filed on March 3, 2003 (the "Priority Date.")

2. When not in use by a patient (either for dose setting or injection), the Vystra is in a resting state in which the setback and the dose set knob are disconnected. The setback and dose set knob are connected only during injection. The connection between setback and dose set knob is disconnected, or released, at the end of the injection process, when the user releases finger pressure on the button.

3. The Vystra tower core has a longitudinal slot that engages with a tab on the plunger rod and provides a keyed connection that has the capacity to prevent the plunger rod from rotating.

4. During the dose setting phase of operation of the Vystra, no drive mechanism

applies rotational force to the plunger rod.

5. Dr. Reinholtz' experiment, in which he cut apart the Vystra, proved nothing about the characteristics of the Vystra as it will be sold.

6. Sanofi offered no credible evidence that, during dose setting, either gravity or vibration cause the Vystra plunger rod to rotate.

7. During dose setting in the Vystra, the rotation of the dose set knob is not transferred to the drive train of the pen. Transfer of rotational movement to the drive train during dose setting is prevented by the operation of the setback's one-way engagement with the brake tower. It is the one-way rachet on the setback that prevents transfer of rotational movement. No other mechanism subjects the plunger rod to rotational force during dose setting.

8. The Vystra setback contains one area that provides clutching functionality, and a different area that provides clicking functionality during dose cancelling. The clutch area of the setback does not provide audible clicks, and the clicker area of the setback does not operate as a clutch.

9. The Vystra contains a dose stop element, which has an external thread and no internal thread.

10. The '844 specification discloses only a nut with an internal thread.

11. Three general purpose dictionaries state that the word "nut" is limited to an object which has an internal thread.

12. The specification of the '844 patent does not describe or depict either an internally threaded piston rod or an externally threaded driving member.

13. No prior art reference discloses an injection pen with an internally threaded piston rod. The prior art did not know how to make an injection pen with an internally threaded piston rod.

14. Modification of the embodiment depicted in the '844 specification to incorporate an internally threaded piston rod would present the POSA with a complicated design task with many choices.

15. A POSA, as of the Priority Date, could not have easily modified the embodiment depicted in the '844 specification to incorporate an internally threaded piston rod.

16. A POSA, as of the Priority Date, would not have been convinced that the inventors of the '844 patent had, at that time, invented an injection pen with an

internally threaded piston rod.

17. Mr. Leinsing's expert testimony about the difficulty a POSA would have encountered in making and using an injection pen with an internally threaded piston rod was conclusory and unsupported by evidence.

18. Mylan presented no evidence regarding the amount of experimentation that would be required for a POSA, relying only on the disclosure of the '844 patent and the knowledge in the art as of the Priority Date, to make and use an injection pen with an internally threaded piston rod.

19. Mylan presented no evidence that a POSA would have had a reason to combine the teachings of SJP and Chanoch to achieve the invention of claim 21.

20. Mylan presented no evidence that a POSA, seeking to achieve the invention of claim 21 by combining the teachings of SJP and Chanoch, would have had a reasonable expectation of success in doing so.

21. Mylan presented no evidence that a POSA, seeking to achieve the invention of claim 22 by combining the teachings of SJP and Chanoch, would have had a reasonable expectation of success in doing so.

22. Mylan presented no evidence that a POSA, seeking to achieve the invention of claim 30 by combining the teachings of SJP and FlexPen, would have had a reasonable expectation of success in doing so.

23. Mylan presented no evidence that a POSA, seeking to achieve the invention of any of claims 21, 22, 25, or 30 by modifying the teachings of FlexPen, would have had a reasonable expectation of success in doing so.

24. The device disclosed in the GiaP reference contains a piston rod holder that is rotatably fixed to the housing during the dose setting phase, and the injection phase, but the piston rod holder is not rotatably fixed to the housing during the cartridge replacement phase of operation.

CONCLUSIONS OF LAW

1. This Court has jurisdiction over this case pursuant to 28 U.S.C. § 1331.

2. The parties accept this Court's personal jurisdiction.

3. Venue is proper in this district pursuant to 28 U.S.C. § 1391(b).

4. "A patent shall be presumed valid. Each claim of a patent (whether in

independent, dependent, or multiple dependent form) shall be presumed valid independently of the validity of other claims; dependent or multiple dependent claims shall be presumed valid even though dependent upon an invalid claim. The burden of establishing invalidity of a patent or any claim thereof shall rest on the party asserting such invalidity." 35 U.S.C. § 282.

5. The claim term, "releasably connected," in claim 21, has its ordinary meaning.

6. The setback and the dose set knob in the Vystra, as it will be distributed, are neither connected nor releasably connected, within the ordinary meaning of "releasably connected" in claim 21. The Vystra does not meet the "releasably connected" limitation contained in claim 21.

7. Claim 21 requires a piston rod holder configured to prevent the piston rod from rotating during dose setting. During dose setting, the flow of rotational force from the dose set knob is interrupted by the operation of the setback's one-way rachet engagement with the brake tower. Because of this, the piston rod holder does not prevent the piston rod from rotating during dose setting. The Vystra piston rod holder, during dose setting, is not configured to prevent the piston rod from rotating during dose setting. The Vystra does not meet the requirement in claim 21 of a piston rod holder configured to prevent the piston rod from rotating during dose setting.

8. The Vystra does not meet two limitations in claim 21. It does not contain a releasably connected sleeve, and it does not contain a piston rod holder configured to prevent the piston rod from rotating during dose setting.

9. Sanofi has failed to prove, by a preponderance of the evidence, that the Vystra contains every limitation in claim 21. The Vystra does not infringe claim 21.

10. Because claims 22, 25, and 30 depend on claim 21, and the Vystra does not infringe claim 21, the Vystra cannot infringe claims 22, 25, and 30.

11. In claim 23, the claim term, "further," has its ordinary meaning. The ordinary meaning of "further" does not imply any requirements in terms of physical separateness or uniqueness.

12. Sanofi has failed to prove, by a preponderance of the evidence, that the Vystra contains a clutch that provides audible clicks during dose cancelling.

13. Sanofi has failed to prove, by a preponderance of the evidence, that the Vystra infringes claim 25.

14. In claim 30, the claim term, "nut," has its ordinary meaning, which is limited to

an object with an internal thread.

15. Sanofi has failed to prove, by a preponderance of the evidence, that the dose stop in the Vystra is a nut, within the ordinary meaning of the term in claim 30.

16. Sanofi has failed to prove, by a preponderance of the evidence, that the Vystra infringes claim 30.

17. The Vystra does not infringe any claim asserted by Sanofi in the ’844 patent.

18. As to an injection pen with an internally threaded piston rod, the ’844 patent specification does not describe such an invention so as to be understandable to a POSA, nor does it show that the inventor possessed that invention.

19. As of the Priority Date, a POSA reading the ’844 patent specification would not be convinced that the inventors possessed an injection pen with an internally threaded piston rod.

20. The disclosure of the ’844 patent does not reasonably convey to those skilled in the art that the inventors had possession of an injection pen with an internally threaded piston rod, as of the Priority Date.

21. Mylan has proven, by clear and convincing evidence, that claim 21 is invalid for failure to meet the written description requirement, pursuant to 35 U.S.C. § 112 ¶ 1.

22. Claim 21 is invalid for failure to meet the written description requirement, pursuant to 35 U.S.C. § 112 ¶ 1.

23. Because claims 22, 25, and 30 depend on claim 21, which Mylan has proven is invalid for failure to meet the written description requirement, pursuant to 35 U.S.C. § 112 ¶ 1, claims 22, 25, and 30 must necessarily also be invalid for failure to meet the written description requirement.

24. As to the “piston rod holder” limitation in claim 21, Mylan has failed to prove, by clear and convincing evidence, that claim 21 is invalid for failure to meet the written description requirement, pursuant to 35 U.S.C. § 112 ¶ 1.

25. Mylan has failed to prove, by clear and convincing evidence, that claim 21 is invalid for failure to meet the enablement requirement, pursuant to 35 U.S.C. § 112 ¶ 1.

26. Claim 21 is not invalid for failure to meet the enablement requirement, pursuant

to 35 U.S.C. § 112 ¶ 1.

27. Claims 22, 25, and 30 are not invalid for failure to meet the enablement requirement, pursuant to 35 U.S.C. § 112 ¶ 1.

28. This Court honors and enforces the IPR Stipulation entered into by the parties, in which Mylan waived these obviousness arguments: 1) obviousness of claims 21 through 29 over SJP alone; and 2) obviousness of claim 30 over SJP in combination with Klitgaard. Although Mylan relied on such arguments in its post-trial briefing, the Court has not considered them.

29. Mylan has failed to prove, by clear and convincing evidence, that claim 21 is invalid as obvious over SJP in view of Chanoch.

30. Mylan has failed to prove, by clear and convincing evidence, that claim 22 is invalid as obvious over SJP in view of Chanoch.

31. Mylan has failed to prove, by clear and convincing evidence, that claim 30 is invalid as obvious over SJP and FlexPen.

32. Mylan has failed to prove, by clear and convincing evidence, that any asserted claim is invalid as obvious over FlexPen.

33. The GiaP reference does not disclose a piston rod holder that is rotatably fixed to the housing during all phases of operation of the device.

34. Mylan has failed to prove, by clear and convincing evidence, that claims 21 or 22 are invalid as obvious over GiaP.

35. Claims 21, 22, 25, and 30 are not invalid as obvious, pursuant to 35 U.S.C. § 103.

36. Claims 21, 22, 25, and 30 of U.S. Patent No. 9,526,844 are invalid for failure to meet the written description requirement stated in 35 U.S.C. § 112 ¶ 1.

37. Defendants' proposed NDA product, the Vystra pen, does not infringe claims 21, 22, 25, or 30 of the '844 patent.

An appropriate Order follows.

s/ Stanley R. Chesler
Stanley R. Chesler, U.S.D.J.

Dated: March 9, 2020